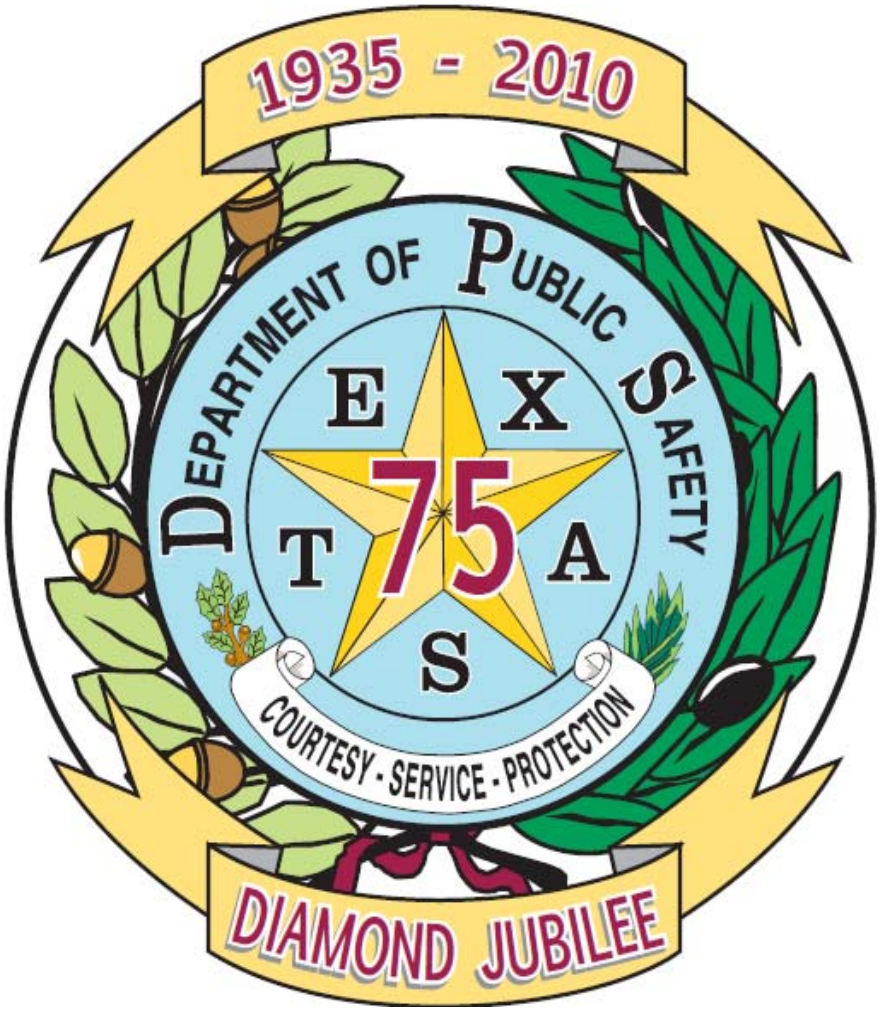
DPS DRUG RULES



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TEXAS ADMINISTRATIVE CODE
Title 37 Public Safety and Corrections
Part I Texas Department of Public Safety
Chapter 13 Controlled Substances

Subchapter A. General Provisions

These rules are current as of March 12, 2008.

§13.1. Chapter Definitions. The following words and terms, when used in this chapter, have the following meanings, unless the context clearly indicates otherwise.

(1) **Act** – The Texas Controlled Substances Act (Texas Health and Safety Code, Chapter 481).

(2) **Administer, abuse unit, adulterant or dilutant, agent, controlled premises, controlled substance, controlled substance analogue, deliver, delivery, designated agent, director, dispense, distribute, distributor, drug, drug paraphernalia, Federal Drug Enforcement Administration, hospital, institutional practitioner, lawful possession, manufacture, marihuana, medication order, narcotic drug, official prescription form, opiate, patient, person, pharmacist, pharmacist-in-charge, pharmacy, possession, practitioner, prescribe, prescription, principal place of business, and registrant** – Have the meanings assigned those terms by the Act, §481.002.

(3) **Advanced Practice Nurse or APN** – An individual recognized as a licensed advances practice nurse by the Texas Board of Nurse Examiners.

(4) **CSR** – Controlled Substances Registration.

(5) **Day** – Means a calendar day unless the context clearly indicates another meaning such as a business day.

(6) **Department or DPS** – The Texas Department of Public Safety.

(7) **Drug Enforcement Administration or DEA** – The Federal Drug Enforcement Administration.

(8) **Electronic Transmission** – The transmission of information in electronic form such as computer to computer, electronic device to computer, e-mail or the transmission of the exact visual image of a document by way of electronic media.

(9) **Emergency Medical Service or EMS** – A person comprised of all needed emergency equipment and trained personnel to administer proper pre-hospital care in a medical or health situation, and licensed as such by the Texas Department of State Health Services.

(10) **Emergency Medical Service Medical Director or EMSMD** – A person recognized as such under Texas Administrative Code, Title 22, Part 9, §197.2 and who has a current DPS registration.

(11) **Emergency Medical Service Provider or EMSP** – A person licensed as such by the Texas Department of State Health Services.

(12) **First Responder Organization or FRO** – An organization certified as such by the Texas Department of State Health Services.

(13) **Health Practitioner** – An individual licensed under the laws of this state to provide health or veterinary services during emergency or disaster situations in this state.

(14) **Individual Practitioner** – A physician, dentist, veterinarian, optometrist, podiatrist, or other individual licensed, registered, or otherwise permitted to dispense a controlled substance in the course of professional practice, but does not include a pharmacist, a pharmacy, or an institutional practitioner.

(15) **Inhalant Paraphernalia** – An item or other material defined as such by Texas Health and Safety Code, §485.001.

(16) **Institutional Practitioner** – A hospital or other person (other than an individual) licensed, registered, or otherwise permitted to dispense a controlled substance in the course of professional practice, but does not include a pharmacy.

(17) **Laboratory Apparatus** – An item subject to Subchapter E of this chapter (relating to Precursors and Apparatus).

(18) **Licensed Vocational Nurse or LVN**--An individual recognized as a licensed vocational nurse by the Texas Board of Vocational Nurse Examiners.

(19) **Locum Tenen** – An individual practitioner who practices in a temporary position in this state and licensed by the appropriate Texas state licensing board.

(20) **Long-term Care Facility or LTCF –** An establishment licensed as such by the Texas Department of Aging and Disability Services.

(21) **Mid-level Practitioner** – An individual practitioner, other than a physician, dentist, veterinarian, optometrist, or podiatrist, who is licensed, registered, or otherwise permitted to dispense a controlled substance in the course of professional practice. Examples of mid-level practitioners include, but are not limited to, health care providers such as advanced nurse practitioners and physician assistants who are authorized to dispense controlled substances.

(22) **Narcotic controlled substance** – A narcotic drug or other controlled substance that contains opium or an opiate derivative.

(23) **Non-narcotic controlled substance** – A controlled substance that does not contain opium or an opiate derivative.

(24) **PCLAS** – The Precursor Chemical/Laboratory Apparatus Section.

(25) **Physician Assistant** – An individual licensed as such by the Texas State Board of Physician Assistant Examiners.

(26) **Precursor chemical** – A substance subject to Subchapter E of this chapter (relating to Precursors and Apparatus).

(27) **Readily retrievable record** – A record created and maintained by an automatic data processing or mechanized record keeping system so that a particular type of record can be separated from all other records in a reasonable time. The term includes a record created and maintained by annotation of each material item with an asterisk, redline, or some other manner visually identifiable apart from all other items appearing on the required record.

(28) **Record** – A notification, order form, statement, invoice, prescription, inventory information, or other document for the acquisition or disposal of a controlled substance, precursor, or apparatus in any manner by a registrant or permit holder under a record keeping or inventory requirement of federal law, the Act, or this chapter.

(29) **Registered Nurse** – An individual recognized as such by the Texas Board of Nurse Examiners.

(30) **Schedule II** – A list of narcotic and non-narcotic controlled substances found in the most current version of Schedule II as established or altered by the commissioner of health under the Act, Subchapter B, and published in the *Texas Register*.

(31) **Stored** – The keeping of controlled substances at a principal place of business. The term does not include the medical lockers in emergency medical vehicles, aircraft (fixed or rotor wing) or vessels while the vehicles, aircraft or vessels are in their stations, hangers or docking stations awaiting calls.

(32) **Temporary Controlled Substances Registration or TCSR** – A controlled substances registration issued to a locum tenen or health practitioner for a period of time not to exceed 90 days.

§13.2. Other State or Federal Laws, Rules, or Regulations. (a) Construed. This chapter may not be construed as authorizing or allowing a person to act in violation of another state or federal law, rule, or regulation. Compliance with this chapter may not be construed as compliance with another state or federal law, rule, or regulation unless expressly provided by the law, rule, or regulation.

(b) Strictest standard. If a practitioner or other person whose conduct is covered by this chapter must comply with a standard contained within a state health regulatory agency rule, this chapter, or a federal regulation, the person must comply with the strictest standard.

(c) Cross-reference. By adopting an administrative rule or regulation of another state or federal agency by a cross-reference to that rule or regulation, the director does not surrender any authority or responsibility to make, administer, or enforce a DPS drug rule. If this chapter references a federal regulation or a rule adopted by another state agency, the director may enforce the regulation or rule:

(1) as a DPS drug rule that has been adopted by the director under the authority of the Act, §481.003; and

(2) as if a reference to:

(A) the DEA administrator or other federal or state official is a reference to the director;

(B) DEA or other agency is a reference to DPS;

(C) a DEA or other agency form is a reference to the analogous DPS form; and

(D) a licensed practical nurse is a reference to a licensed vocational nurse.

§13.3. Alternative Schedule Nomenclature. The director may reference a schedule for a controlled substance by:

(1) its statutory Roman numeral designation; or

(2) an analogous Arabic number designation.

§13.4. Notification, Information, and Electronic Transmission. (a) Notification. If this chapter requires a person to notify or advise the director of new or changed information, the person must notify the director through the appropriate DPS unit indicated in this chapter. If this chapter describes the director followed by a parenthetical reference to a section, service, or other unit of the department, the communication will be made to the director through the referenced section, service, or unit.

(b) Information. The director may furnish information about this chapter to a person who has made a personal, telephonic, or written request to the director through the appropriate service or section.

(c) Forms. The director may:

(1) provide internet access to a form used under this chapter; or

(2) accept an internet application under this chapter.

(d) Signature or ID. The director may accept an electronically transmitted signature or other similar identification code under this chapter.

§13.5. Acceptance of Non-standard Communication. The director may accept an oral, telephonic, electronic, or other non-standard communication as sufficient to meet a reporting or notification requirement of this chapter if:

(1) the oral, telephonic, electronic, or other communication is repeated in an original writing within seven days after the initial electronic report or notification; or

(2) an expressly named representative of the director waives the written report or notification otherwise required to confirm the communication.

§13.6. Waiver Rescission. The director may rescind a waiver issued under this chapter if the reason for the waiver no longer exists.

§13.7. Telephone Number and Address – Narcotics Regulation Bureau. To inquire about information and administrative matters with, transmit to, or otherwise contact the Narcotics Regulation Bureau, in general:

(1) the telephone number is: (512) 424-2188 or 424-2189;

(2) the fax number is: (512) 424-5799 or 424-5373;

(3) the Post Office Box mailing address is: Narcotics Regulation Bureau MSC 0439, Texas Department of Public Safety, PO Box 4087, Austin, Texas 78773-0439; and

(4) the physical mailing address is: Narcotics Regulation Bureau MSC 0439, Texas Department of Public Safety, 5805 N. Lamar Blvd., Austin, Texas 78752-4422.

§13.8. Telephone Number and Address – Controlled Substances Registration Section. To inquire about information and administrative matters with, transmit to, or otherwise contact the Controlled Substances Registration (CSR) Section:

(1) the telephone number is: (512) 424-2188;

(2) the fax number is: (512) 424-5799;

(3) the Post Office Box mailing address is: Controlled Substances Registration Section MSC 0438, Texas Department of Public Safety, P.O. Box 4087, Austin, Texas 78773-0438;

(4) the fee or payment address is: Controlled Substances Registration Section MSC 0438, Texas Department of Public Safety, P.O. Box 15999, Austin, Texas 78761-5999;

(5) the physical mailing address is: Controlled Substances Registration Section MSC 0438, Texas Department of Public Safety, 5805 N. Lamar Blvd., Austin, Texas 78752-4422; and

(6) the e-mail address is through the department's web page at "www.txdps.state.tx.us" or directly through “tppcsr@txdps.state.tx.us.”

§13.9. Telephone Number and Address – Texas Prescription Program. To inquire about information and administrative matters with, transmit to, or otherwise contact the Texas Prescription Program:

(1) the telephone number is: (512) 424-2189;

(2) the fax number is: (512) 424-5373;

(3) the Post Office Box mailing address is: Texas Prescription Program MSC 0439, Texas Department of Public Safety, P.O. Box 4087, Austin, Texas 78773-0439;

(4) the fee or payment address is: Texas Prescription Program MSC 0439, Texas Department of Public Safety, P.O. Box 15999, Austin, Texas 78761-5999;

(5) the physical mailing address is: Texas Prescription Program MSC 0439, Texas Department of Public Safety, 5805 N. Lamar Blvd., Austin, Texas 78752-4422; and

(6) the e-mail address is through the department's web page at "www.txdps.state.tx.us" or directly through "tppcsr@txdps.state.tx.us."

§13.10. Telephone Number and Address – Precursor Chemical/Laboratory Apparatus Section. To inquire about information and administrative matters with, transmit to, or otherwise contact the Precursor Chemical/Laboratory Apparatus Section (PCLAS):

(1) the telephone number is: (512) 424-2481 or (512) 424-2482;

(2) the fax number is: (512) 424-5799;

(3) the Post Office Box mailing address is: Precursor Chemical/Laboratory Apparatus Section MSC 0433, Texas Department of Public Safety, P.O. Box 4087, Austin, Texas 78773-0433;

(4) the physical mailing address is: Precursor Chemical/Laboratory Apparatus Section MSC 0433, Texas Department of Public Safety, 5805 N. Lamar Blvd., Austin, Texas 78752-4422; and

(5) the e-mail address is through the department's web page at "www.txdps.state.tx.us" or directly through "precursor.chemical @txdps.state.tx.us."

§13.11. Telephone Number and Address – Crime Laboratory Service. To inquire about information and administrative matters with, transmit to, or otherwise contact the Crime Laboratory Service:

(1) the telephone number is: (512) 424-2105;

(2) the fax number is: (512) 424-2869;

(3) the Post Office Box mailing address is: Crime Laboratory Service MSC 0460, Texas Department of Public Safety, P.O. Box 4143, Austin, Texas 78765-0460; and

(4) the physical mailing address is: Crime Laboratory Service MSC 0460, Texas Department of Public Safety, 5805 N. Lamar Blvd., Austin, Texas 78752-4422.

Subchapter B. Registration

§13.21. Who Must Register. (a) Required by Act. A person, who is required by the Act to register in order to manufacture, distribute, prescribe, possess, analyze, dispense, or conduct research with a controlled substance, must obtain an annual registration from the director (CSR Section).

(b) Generally. Only a person actually engaged, in this state, in an activity covered by the registration provisions of the Act must obtain a registration. A related or affiliated person who is not engaged in a covered activity is not required to register.

(c) Activities. The director may register a person for one or more of the following categories of business activity:

(1) practitioner;

(2) pharmacy;
(3) hospital;
(4) manufacturer;
(5) researcher;
(6) teaching institution;
(7) distributor;
(8) analyst or analytical lab;
(9) EMSP;
(10) peyote distributor; or
(11) mid-level practitioner.

(d) Schedules. The director may register a person for one or more of the following schedules:

(1) Schedule I;
(2) Schedule II (narcotic);
(3) Schedule II (non-narcotic);
(4) Schedule III (narcotic);
(5) Schedule III (non-narcotic);
(6) Schedule IV; or
(7) Schedule V.

(e) Lawful possession. A registrant may lawfully possess a controlled substance to the extent authorized by the registration.

(f) An applicant may apply for registration as a manufacturer, researcher, teaching institution, distributor, analyst, or analytical laboratory only after obtaining the appropriate registration from DEA.

§13.22. Registration for Certain Activities. (a) Schedule I.

(1) A person who is seeking registration to conduct research with a Schedule I controlled substance must comply with the Act, §481.065(b) and submit a research protocol to the director for approval. Under this subsection, the person may submit a duplicate of a protocol submitted to DEA for the same research authority. Once submitted, the protocol becomes a part of the application for all purposes. If approved by the director, the person may conduct research only:

(A) in the manner expressly detailed in the protocol; and
(B) using a controlled substance expressly specified in the protocol.

(2) Without DEA registration. If the director determines registration is appropriate to minimize a risk of diversion or abuse of a controlled substance, the director may register a person who:

(A) has not applied for registration with DEA; or
(B) is not a registrant with DEA.

(b) Schedules II - V.

(1) A person who is seeking registration to possess, prescribe or dispense a Schedule II - V controlled substance must comply with the Act, §481.061.

(2) A provider pharmacy of a long term care facility must comply with the Texas Pharmacy Act and rules.

§13.23. Separate Registration for Separate Location. An applicant must make a separate application and obtain a separate registration for each principal place of business or professional practice as required by the Act, §481.061(c) and the Code of Federal Regulations, Title 21, Chapter II, §1301.12.

§13.24. Exemption from Registration. A person is exempt from registration, need not register, and may lawfully possess a controlled substance under the Act if the person is:

(1) exempted from registration under the Act, §481.062;

(2) excepted from the Act, Subchapter C, under the Act, §481.0621; or

(3) exempted from federal registration under the Code of Federal Regulations, Title 21, Chapter II, §§1301.22 - 1301.24.

§13.25. Application. (a) Required. A person required to register under this subchapter must comply with this subchapter and Subchapter F of this chapter (relating to Applications).

(b) Form. An applicant must make:

(1) a new or original application on DPS Form NAR-77, NAR-77a, or NAR 77b;

(2) a renewal application on DPS Form NAR-78 or NAR-78a; or

(3) a TCSR application on DPS Form NAR-77 or NAR-77a.

(c) Rejection. An applicant who seeks to renew a registration may correct a rejected or defective application and resubmit it for filing at any time before termination under §13.30 of this title (relating to Termination).

§13.26. Certificate. (a) Issuance. The director will issue a certificate of registration to an applicant who qualifies for registration or renewal under the applicable provisions of the Act, Subchapter C, and this subchapter.

(b) NAR-79. The director will issue a certificate to a registrant listed in §13.21(c)(1) - (9) of this title (relating to Who Must Register) on DPS Form NAR-79, containing:

(1) the registrant's name and address;

(2) the registration number;

(3) the business activity authorized by the registration;

(4) each schedule the registrant is authorized to handle;

(5) a "paid" or "exempt" notation;

(6) a "duplicate" notation, if the certificate is a duplicate;

(7) the certificate's issue date; and

(8) the certificate's expiration date.

(c) NAR-79a. The director will issue a certificate to a mid-level practitioner on DPS Form NAR-79a, containing:

(1) the information listed in §13.26(b) of this title (relating to Certificate); and

(2) the name of the supervising physician delegating prescriptive authority or the EMSMD.

(d) Display. The registrant must:

(1) display the certificate at the physical location of the registrant's principal place of business; or

(2) maintain the certificate so the registrant may promptly retrieve and display it at any time upon proper demand.

§13.27. Fees. (a) Amounts. To apply for an original or renewal registration to manufacture, distribute, prescribe, possess, analyze, dispense, or conduct research with a controlled substance, the applicant must pay a non-refundable processing fee of $25.

(b) Submission. An applicant must submit the fee with the original or renewal application to the director (CSR Section).

(c) Acceptable manner. The applicant must make payment in the form of a check or money order, payable to the "Texas Department of Public Safety," or another form of payment authorized by a general rule or policy of the department.

(d) Prohibited manner. The director will not accept a fee payment in the form of:

(1) stamps;

(2) foreign currency;

(3) a check or money order, payable in foreign currency; or

(4) a third-party endorsed check.

(e) Multiple or additional fees. The director:

(1) may charge multiple fees for registrations to one person at each different location and for each different business activity; and

(2) will not charge an additional fee for each different schedule processed on a single registration application.

(f) Late renewal application fee. The director may charge a late fee of $50 for each renewal application received after the date of expiration of the annual registration.

§13.28. Fee Exemption. (a) Requirements. The director may exempt a person from payment of a state fee for registration or renewal, if the person's superior certifies on the DPS Form NAR-77, NAR-77a, NAR-77b, NAR-78, or NAR-78a that the person is exempted from payment of a fee under the Code of Federal Regulations, Title 21, Chapter II, §1301.21 and is registered in Texas.

(b) Effect. Exemption from payment of a new registration or renewal fee:

(1) authorizes the registrant, where applicable, to acquire, possess, or handle a controlled substance only at the exempt location; and

(2) does not relieve the registrant of another requirement or duty prescribed by law.

§13.29. Expiration. (a) Annual. Except as provided by subsection (c) of this section, an original certificate of registration expires after one year from the month of issuance indicated on the original certificate.

(b) Effect of modification or renewal. Except as provided by subsection (c) of this section, a modification in registration or an early renewal does not affect a current or future date of expiration.

(c) Extension. The director may extend the expiration date of a registration for a period of less than 12 additional months, if the director determines the extension is necessary to evenly allocate the expiration dates of all certificates.

(d) Effect of expiration. After expiration, the former registration provides the registrant with no authority to manufacture, distribute, prescribe, possess, analyze, dispense, or conduct research with a controlled substance.

(e) Renewal of expired number. After expiration under this section, a former registrant may apply for a new registration. During a six-month period after expiration and before

termination under §13.30(a)(1) of this title (relating to Termination), the director (CSR Section) may reserve the original registration number in the name of the original applicant.

§13.30. Termination. (a) When. A registration terminates:

(1) at the end of six months after expiration;

(2) upon expiration of a TCSR;

(3) when a regulatory board or DEA accepts a voluntary surrender, or denies, suspends, or revokes a license or a federal controlled substance registration; or

(4) when the person dies, ceases legal existence, or discontinues business or professional practice.

(b) New registration required. After termination, a former registrant must apply for a new registration and may be issued a different registration number.

(c) Effect of termination. After termination, the former registration provides the registrant with no authority to manufacture, distribute, prescribe, possess, analyze, dispense, or conduct research with a controlled substance.

(d) Discontinued activity. On the day a registrant discontinues business or professional practice, the registrant or a representative of the registrant must notify the director (CSR Section) by close of business. The director may immediately terminate the registration of a person reported to the director under this subsection.

(e) Mid-level practitioner. Upon dissolution of a professional relationship between a mid-level practitioner and the delegating physician, the mid-level practitioner has no authority to distribute, prescribe, possess, or dispense a controlled substance. If the mid-level practitioner does not have a new delegating physician certifying delegation within 60 days after the dissolution of such relationship, the director may terminate the registration of the mid-level practitioner.

(f) Return certificate. A registrant must return a terminated certificate within 30 days after termination if the certificate is not expired.

§13.31. Security, Record Keeping, Inventory, Inspection, and Reporting Discrepancy, Loss, Theft, or Diversion. A registrant must comply with the applicable provisions of:

(1) Subchapter H of this chapter (relating to Security);

(2) Subchapter I of this chapter (relating to Record Keeping);

(3) Subchapter J of this chapter (relating to Inventory);

(4) Subchapter K of this chapter (relating to Inspection); and

(5) Subchapter L of this chapter (relating to Reporting Discrepancy, Loss, Theft, or Diversion).

§13.32. Communication with Director (CSR Section). If a person is required or allowed by this subchapter to make a notification, report, or other written, telephonic, or personal communication to the director, the person must make the communication to the director through the CSR Section at the address indicated in §13.8 of this title (relating to Telephone Number and Address - Controlled Substances Registration Section).

§13.33. Miscellaneous. (a) Confidentiality. A person lawfully authorized under this chapter to conduct research in the use and effects of a controlled substance may, under the Act, §481.068,

withhold from the director the name and other identifying characteristics of an individual who is the subject of the research.

(b) Transfer. A registrant may not transfer or assign to another person a registration certificate or an authority conferred by the registration.

Subchapter C. Peyote

§13.41. Subchapter Definitions. The following words and terms, when used in this subchapter, have the following meanings, unless the context clearly indicates otherwise.

(1) **AIRFA** –The American Indian Religious Freedom Act.

(2) **Distributor** – A peyote distributor registered by the director under this subchapter and Subchapter B of this chapter (relating to Registration).

(3) **Identification information** – A unique number appearing on the individual's:

(A) driver license or personal identification certificate and assigned to the individual by the department or by an analogous agency in another state; or

(B) social security card, military identification card, passport, visa, work permit, or other identification card and assigned to an individual by an agency of the United States.

(4) **Indian** – An individual with not less than 25% Indian blood who is declared by a Native American Church to be a member of the church.

(5) **Landowner** – Includes an agent of the landowner.

§13.42. Peyote Distributor Registration. (a) Who must register. A person who delivers peyote must make application for a controlled substances registration under the Act and obtain an annual registration from the director (CSR Section).

(b) Effect of registration. A distributor seeking to deliver or receive peyote under this subchapter may obtain a peyote distributor registration that authorizes the distributor to:

(1) deliver peyote to another distributor;

(2) receive peyote from another distributor;

(3) receive peyote from an employee of the distributor; or

(4) deliver peyote to an Indian for use only in a bona fide religious ceremony of the church.

(c) Activity authorized. Incidental to lawful distribution under this subchapter, a distributor may hunt, harvest, cut, collect, transport, or possess peyote.

(d) Activity not authorized. A distributor registration does not authorize the distributor to:

(1) manufacture or cultivate peyote;

(2) ingest or use peyote;

(3) deliver to an individual who is an Indian as the term is defined in AIRFA, unless the individual is also an Indian as the term is defined in this subchapter; or

(4) import or export peyote except as permitted by federal law.

§13.43. Application. (a) Requirements. The director may register and issue a certificate of registration to a distributor only if the applicant:

(1) meets the general requirements for a controlled substances registration under Subchapter B of this chapter (relating to Registration);

(2) is registered with DEA;

(3) has made a complete application to the director (CSR Section) for registration as a distributor on DPS Form NAR-95 and complied with this section and Subchapter F of this chapter (relating to Applications);

(4) has paid the required registration fee; and

(5) forwards with the application for registration a letter from the local chief of police, sheriff, or county judge in the jurisdiction where the applicant's principal place of peyote business is located stating the applicant is of good moral character.

(b) Fee. The fee for registration as a distributor is the same amount as the fee collected for a controlled substances registration under §13.27 of this title (relating to Fee).

§13.44. Certificate and ID Card. (a) Issuance. If the director approves an application for registration, the director will issue to the applicant:

(1) a certificate of registration, DPS Form NAR-96; and

(2) a peyote distributor identification card, DPS Form NAR-96A.

(b) Return. If the director suspends, revokes, denies, cancels, or accepts voluntary surrender of a distributor's certificate of registration, the distributor must return the following to the director (CSR Section) within seven days:

(1) the peyote distributor certificate of registration;

(2) the peyote distributor identification card;

(3) each peyote employee identification card;

(4) each unused or voided sale of peyote receipt, DPS Form NAR-96C; and

(5) each completed receipt or other document relating to the purchase, acquisition, or sale of peyote not already submitted to the director.

(c) Expiration. The director will issue a certificate of registration and a peyote distributor identification card to expire in the same manner as a controlled substances registration under §13.29 of this title (relating to Expiration).

(d) Display. The distributor must display the certificate of registration at all times in a conspicuous place at the address appearing on the certificate.

§13.45. Employee Information. (a) Identification. A distributor must furnish to the director (CSR Section) the name and identification information of each current employee who will:

(1) handle or possess peyote in the course and scope of employment; and

(2) use that employment status to avoid potential criminal liability for handling or possessing peyote.

(b) Current employee. A distributor or applicant must provide to the director (CSR Section) on an application for original or renewal of registration a list of the name and other identification information of an individual who is:

(1) currently employed by the distributor; or

(2) reasonably known to the distributor as likely to be employed during the term of the registration sought by the applicant.

(c) New employee. If a new employee's name and other identification information has not already been indicated on a distributor's current application for registration, then, before the employee is allowed to work handling or possessing peyote, the distributor must:

(1) advise the director (CSR Section) of the change; and

(2) receive a peyote employee identification card, DPS Form NAR-96B.

§13.46. Employee Identification Card. (a) Form. After notification by a distributor, the director will furnish the distributor a peyote employee identification card, DPS Form NAR-96B. The distributor may give notice under this subsection for an employee already named in the application or a new employee named at a later date.

(b) Use of ID card. The peyote employee identification card certifies the individual named is:

(1) an employee of the distributor;

(2) authorized to hunt, harvest, cut, collect, transport, or possess peyote in the course and scope of employment; and

(3) authorized to deliver peyote, but only directly to the distributor who employs the individual.

(c) Retrieval and return. When an employee ceases employment with a distributor, the distributor must take reasonable steps to:

(1) by close of business, retrieve the employee identification card from the employee; and

(2) within seven days:

(A) return the card to the director (CSR Section) for cancellation; or

(B) notify the director (CSR Section) of the reason the card was not retrieved or returned, including the reasonable steps taken by the distributor while attempting to do so.

§13.47. Possession and Display of Identification and Access Information. (a) Possession. At all times an employee is hunting, harvesting, cutting, collecting, transporting, or in possession of peyote, the employee must possess a peyote employee identification card.

(b) Demand of official. When a distributor or employee is hunting, harvesting, cutting, collecting, transporting, or in possession of peyote, the individual must:

(1) possess a current, valid distributor or employee identification card; and

(2) display the card upon demand to the director or a member of the department, a peace officer, or a federal official.

(c) Demand of landowner. If the distributor or employee is hunting, harvesting, cutting, collecting, transporting, or in possession of peyote on land belonging to someone other than the distributor or employee, the distributor or employee must display the card upon demand to the landowner.

(d) Supporting documentation. If an individual is required to display an identification card under this section, the individual must also possess and display a license, card, or other documentation to support identification information contained on the distributor or employee identification card and:

(1) documentation sufficient to show lawful access to the land where the peyote was harvested or cut; or

(2) a reasonably complete verbal declaration of the individual's lawful access to the land, including the name and location of the person granting the access.

(e) Manner of compliance. An individual may comply with subsection (d)(1) of this section by presenting an original or copy of an ownership document, lease agreement, or other document showing the individual's lawful access to the land in question.

§13.48. Source Information. (a) Notification of director. A distributor must notify the director (CSR Section) of the name of the owner and the physical address or other sufficient description of all land to which the distributor has legal access for harvesting peyote. The notification must be made at the time of registration and within seven days of a change in the information required by this section.

(b) Ensure lawful access. A distributor may not deliver peyote to another distributor or an Indian unless the distributor takes reasonable steps to ensure the peyote was harvested or cut in Texas by the distributor or an employee of the distributor on land to which the distributor has a legal right of entry. The director will deem a distributor has taken reasonable steps under this subsection if the distributor:

(1) makes express verbal inquiry about the source of all peyote supplied to the distributor by an employee or another distributor; and

(2) obtains from the employee or other distributor a verbal or written statement certifying the source of all peyote supplied to the distributor.

§13.49. Purchase or Harvest. (a) Requirements, generally. An Indian may purchase peyote in person from a distributor in this state if the Indian follows one of the methods described by §13.50 of this title (relating to Sale in Person) or §13.51 of this title (relating to Mail Order Sale). The director encourages but does not require use of the standard method.

(b) Harvesting by Indian. A landowner may not allow an Indian to harvest peyote on the land of another person unless the Indian furnishes to the landowner a letter, permit, or identification sufficient to comply with either subsections (c) or (g) of §13.50 of this title (relating to Sale in Person).

§13.50. Sale in Person. (a) Requirements, generally. A distributor may not supply or sell peyote to a person unless the person is:

(1) another registered peyote distributor;

(2) a governmental entity or a person registered with the director in a capacity to lawfully receive the peyote; or

(3) an Indian who complies with this subchapter.

(b) The distributor delivering peyote to an Indian must follow one of the methods described by this section or §13.51 of this title (relating to Mail Order Sale). The director encourages but does not require use of the standard method.

(c) Standard method. A distributor may deliver peyote to an Indian member of the Native American Church if the purchasing Indian furnishes to the distributor identification that includes reasonably accurate identification information and a travel permit. The identification and the permit must collectively contain the full name, including Indian name, degree of Indian blood (not less than 25%), and date of birth of the purchasing or harvesting Indian.

(d) Required contents. A travel permit, that is used in the standard method, must:

(1) be printed on official stationery of the Native American Church; and

(2) contain the following:

(A) the full name and either a cross-reference to an identification card number or some other reasonably accurate identification of the purchasing or harvesting Indian;

(B) the date of issuance and expiration for the permit; and

(C) the signature of the president, vice president, or other designated custodian of the state or local organization of the Native American Church who personally issued the permit to the purchasing or harvesting Indian.

(e) Recommended contents. The director encourages but does not require that a travel permit, that is used in the standard method, contain the following:

(1) the estimated or probable dates, routes, and mode of travel, that may include a detailed description of a vehicle and its occupants;

(2) the estimated location of purchase (or harvest); and

(3) the estimated amount of peyote to be purchased (or harvested).

(f) Timely transmission. A church representative should timely mail or cause to be mailed or otherwise transmit electronically to the director (CSR Section) a permit described by subsections (d) and (e) of this section. The director will deem a permit to be timely mailed if it is on file with the director before anyone attempts to purchase or harvest peyote under its authority. If the CSR Section receives the permit before the distributor delivers the peyote, the director may then respond knowledgeably to an inquiry made about the legitimacy of the peyote purchase, harvest, possession, or transportation even if some of the prospective information reported under subsection (e) of this section may have changed.

(g) Alternative method. In lieu of the standard method documentation required by this section, a distributor may deliver peyote to an Indian member of the Native American Church if the purchasing Indian furnishes identification that includes reasonably accurate identification information and:

(1) a birth certificate or other document showing the purchasing or harvesting Indian's full name, including Indian name, tribe, degree of Indian blood (not less than 25%), date of birth, agency enrolled with, and census number or enrollment number; and

(2) an authorization letter signed by the president, vice president, or other designated custodian of the state or local organization of the Native American Church certifying:

(A) the purchasing or harvesting Indian is a member in good standing of the state or local organization of the Native American Church; and

(B) the peyote to be purchased or harvested will be used only for a bona fide religious ceremony.

(h) Transmission. If a church contemplates using the alternative method, a church representative should mail the documentation described by subsection (g) of this section to the director (CSR Section). If the director (CSR Section) receives the documentation before the distributor delivers the peyote, the director may then respond knowledgeably to an inquiry made about the legitimacy of the peyote purchase, harvest, possession, or transportation.

(i) A church may request a copy of a sample authorization letter or travel permit from the director.

§13.51. Mail Order Sale. (a) Requirements. In the case of a mail order sale, the distributor must:

(1) notify the director (CSR Section) in writing of each peyote mailing;

(2) obtain the information required by paragraph (3) of this subsection in writing on appropriate church stationery, including a copy of the recipient's authorization letter or travel permit from a church;

(3) prepare a sales receipt as required by §13.52 of this title (relating to Sales Receipt), except:

(A) the distributor must clearly mark the sales receipt to indicate a mail order transaction;

(B) the recipient's signature need not appear on the original receipt;

(C) the recipient's signature must appear on the original documentation certifying eligibility to lawfully receive peyote as an Indian;

(D) the original documentation certifying eligibility must include the mailing address at which the Indian will receive the peyote; and

(E) the distributor must include the second copy (Copy 2) of the receipt on or within the mailed package containing the peyote; and

(4) mail to the director the original sales receipt (Copy 1) and a copy of its associated documentation at the same time the distributor mails the peyote, not waiting for the due date of the next quarterly report.

(b) Recommendations. The director encourages but does not require that a distributor not mail the peyote until after the director receives the written notification. If the director (CSR Section) receives the distributor's receipt and its associated documentation before the distributor mails the peyote, the director (CSR Section) may then respond knowledgeably to an inquiry made about the legitimacy of the peyote shipment.

(c) Manner required. A distributor must mail an order for peyote only by using:

(1) the distributor's principal place of business as the return address; and

(2) the United States Postal Service, certified mail, return receipt requested; or

(3) another parcel distribution system that minimizes the risk of diversion by:

(A) restricting delivery to the individual placing the order; or

(B) adequately identifying the individual to whom delivery was made.

(d) Manner prohibited. A distributor may not mail an order for peyote to:

(1) a person other than the Indian placing the order at the address indicated for the Indian in the associated documentation; or

(2) a third party.

§13.52. Sales Receipt. (a) Requirements, generally. A distributor must furnish the original sales receipt (Copy 1) to the director on DPS Form NAR-96C.

(b) Contents. Each sales receipt must contain the following:

(1) the distributor's name;

(2) the distributor's registration number;

(3) the date of sale;

(4) the name, address, and blood quantum of the purchasing Indian;

(5) the purchasing Indian's church affiliation;

(6) for the purchasing Indian:

(A) the church membership number;

(B) the travel permit number; or

(C) the issue date of the authorization letter;

(7) the quantity purchased, expressed as either the number of buttons or the weight in pounds and ounces;

(8) the total cost of sale; and

(9) except in the case of a mail order sale, the purchasing Indian's signature.

(c) Multiple copies. A distributor must:

(1) submit the original copy (Copy 1) of the receipt to the director with the quarterly report;

(2) furnish the second copy (Copy 2) of the receipt to the purchasing Indian at the time of the purchase; and

(3) retain the third copy (Copy 3) in the distributor's permanent files.

§13.53. Quarterly Report. (a) When made. A distributor must furnish a quarterly report to the director of each purchase, acquisition, or sale made by the distributor during the previous quarter. A distributor must submit a quarterly report even if no purchase, acquisition, or sale occurred during the quarter.

(b) Contents. The report must include a tabulation of total purchases, acquisitions, and sales of peyote, tabulated by price and by number of buttons or weight. Along with the report, the distributor must provide to the director (CSR Section) a copy of all:

(1) certificates, logs, or other documents showing each act of purchase or acquisition of peyote by the distributor; and

(2) receipts issued for sale of peyote, DPS Form NAR-96C, except those mail order sale receipts already forwarded to the director.

(c) Manner of report. The distributor must:

(1) furnish the report to the director (CSR Section); and

(2) submit the report on or before the last business day of:

(A) April (for purchases, acquisitions, or sales during the first quarter of the year, including the preceding months of January, February, and March);

(B) July (for purchases, acquisitions, or sales during the second quarter of the year, including the preceding months of April, May, and June);

(C) October (for purchases, acquisitions, or sales during the third quarter of the year, including the preceding months of July, August, and September); and

(D) January (for purchases, acquisitions, or sales during the fourth quarter of the previous year, including the preceding months of October, November, and December).

§13.54. Declaration as Native American Church. (a) While the director does not require an entity to seek recognition or registration as a church, an entity, that seeks to declare itself to the director under this subchapter as a Native American Church, must submit and update the following information to the director (CSR Section):

(1) the state charter; and

(2) the identity of its president, vice president, and other designated custodian or current officer, including the full name, Indian name, degree of Indian blood, date of birth, address, and telephone number of each custodian or officer.

(b) In addition to the information submitted to the director under subsection (a) of this section, the entity may submit the following additional identifying information about each custodian or officer:

(1) tribe;

(2) agency enrolled with; and

(3) census number or enrollment number.

§13.55. Landowner Activity. (a) Unaffected. Nothing in this subchapter affects the ability of a landowner to:

(1) file a criminal trespass, criminal mischief, theft, or other appropriate criminal charge or to seek other criminal or civil remedy; or

(2) burn or clear land for purposes unrelated to harvesting, cutting, collecting, or possessing peyote.

(b) Prohibited. Unless registered as a distributor or reported to the director as a current employee of a distributor, a landowner may not sell, harvest, cut, collect, transport, or possess peyote. A landowner does not possess peyote in violation of the Act or this subchapter if the peyote is unharvested and growing in its natural state.

(c) Allowed. Under this subchapter, a landowner may:

(1) charge a fee to anyone, including an Indian, for the use of or entry onto land;

(2) allow a distributor or employee of a distributor to enter land to harvest peyote;

(3) deliver or otherwise supply peyote to a distributor as described in subsection (b) of this section; or

(4) deliver or supply peyote to an Indian only:

(A) by allowing the Indian to enter land to harvest or use peyote; and

(B) if the Indian would otherwise be allowed to purchase peyote from a distributor under this subchapter.

(d) Harvest fee limitation. Unless the landowner is registered as a distributor, the director will deem the landowner to be selling or distributing peyote if the landowner bases the fee charged or collected under subsection (c)(1) of this section on the amount of peyote harvested, cut, or collected by the Indian using or entering the land.

§13.56. Security, Record Keeping, Inventory, Inspection, and Reporting Discrepancy, Loss, Theft, or Diversion. A distributor must comply with the applicable provisions of:

(1) Subchapter H of this chapter (relating to Security);

(2) Subchapter I of this chapter (relating to Record Keeping);

(3) Subchapter J of this chapter (relating to Inventory);

(4) Subchapter K of this chapter (relating to Inspection); and

(5) Subchapter L of this chapter (relating to Reporting Discrepancy, Loss, Theft, or Diversion).

§13.57. Communication with Director (CSR Section). If a person is required or allowed by this subchapter to make a notification, report, or other written, telephonic, electronic, or personal communication to the director, the person must make the communication to the director through the CSR Section at the address indicated in §13.8 of this title (relating to Telephone Number and Address--Controlled Substances Registration Section).

§13.58. Miscellaneous. (a) Peyote in another jurisdiction unaffected. Nothing in this subchapter allows, prohibits, or otherwise affects the ability of a person to deliver, supply, sell, hunt, harvest, cut, collect, transport, or possess peyote in:

(1) another state or country, including Mexico or Canada, while acting under the authority of that jurisdiction; or

(2) Texas while acting under the authority of federal law, if the peyote was obtained from Mexico.

(b) AIRFA. Nothing in this subchapter affects the ability of an individual to use, possess, or transport peyote under federal law, if the individual:

(1) is an Indian of any blood quantum as the term Indian is defined in AIRFA;

(2) is a member of an Indian tribe; and

(3) intends to use the peyote for bona fide traditional ceremonial purposes in connection with the practice of a traditional Indian religion.

(c) Registration subchapter applies. Except as otherwise provided by this subchapter, Subchapter B of this chapter (relating to Registration) applies to a peyote registration under this subchapter.

Subchapter D. Texas Prescription Program

§13.71. Subchapter Definitions. The following words and terms, when used in this subchapter, have the following meanings, unless the context clearly indicates otherwise.

(1) **Emergency situation** – A situation described in the Code of Federal Regulations, Title 21, Chapter II, §1306.11(d).

(2) **NDC # -** A National Drug Code number.

(3) **Reportable prescription** – A prescription for a controlled substance:

(A) listed in Schedules II through V; and

(B) not excluded from this subchapter by a rule adopted under the Act, §481.0761(b).

(4) **Prescription** – A controlled substance prescription as defined in Section 481.002(41).

§13.72. Official Prescription Program. (a) Who may order form. A practitioner may order a quantity of official prescription forms from the director only if the practitioner is registered by the director and DEA under both state and federal law to prescribe a Schedule II controlled substance.

(b) Source. A practitioner may order the forms from the director (Texas Prescription Program).

(c) Institutional practitioner. This subsection applies only to an individual who is employed by a hospital or other training institution that is registered by the director. An institutional practitioner, who is authorized by a hospital or institution to prescribe a Schedule II controlled substance under the registration of the hospital or institution, may order official prescription forms under this section, if:

(1) the practitioner prescribes a controlled substance in the usual course of the practitioner's training, teaching program, or employment at the hospital or institution;

(2) the appropriate state health regulatory agency has assigned an institutional permit or similar number to the practitioner; and

(3) the hospital or institution:

(A) maintains a current list of each institutional practitioner and each assigned institutional permit number; and

(B) makes the list available to another registrant or a member of a state health regulatory or law enforcement agency for the purpose of verifying the authority of the practitioner to prescribe the substance.

§13.73. Form. (a) Use. A practitioner may issue a prescription for a Schedule II controlled substance only on an official Texas prescription form, which includes single or multiple copy forms. This subsection also applies to a prescription issued in an emergency situation.

(b) Refills prohibited. A Schedule II prescription may not be refilled.

(c) Completion. A practitioner who prescribes any quantity of a Schedule II controlled substance must complete an official prescription form by legibly filling in the spaces provided.

(d) Issuance of multiple Schedule II prescriptions. A practitioner may issue multiple prescriptions authorizing a patient to receive a total up to a 90-day supply of a Schedule II controlled substance provided:

(1) each separate prescription is issued for a legitimate medical purpose while practitioner is acting in the usual course of professional practice;

(2) the practitioner provides written instructions on each prescription (other than the first prescription; the first prescription is intended to be filled within 21 days of issuance) indicating the earliest date on which a pharmacy may fill each prescription.

(3) the practitioner concludes that providing the patient with multiple prescriptions in this manner does not create an undue risk of diversion or abuse; and

(4) the individual practitioner complies fully with all other applicable requirements under the Health and Safety Code, Chapter 481 and these regulations.

(e) Other requirements. A practitioner:

(1) may not postdate an official prescription;

(2) must ensure all information on the prescription is legible on all copies, including stamped or preprinted instructions;

(3) must include an “earliest fill date” on all multiple issued prescriptions; and

(4) must sign and date the prescription only when issued.

§13.74. Exceptions to Use of Form. (a) Medication order. An official prescription form is not required for a medication order written for a patient who is admitted to a hospital at the time the medication order is written and filled.

(1) A practitioner may dispense or cause to be dispensed a Schedule II controlled substance to a patient who:

(A) is admitted to the hospital; and

(B) will require an emergency quantity of a controlled substance upon release from the hospital.

(2) Under paragraph (1) of this subsection, the controlled substance:

(A) may only be dispensed in a properly labeled container; and

(B) may not be more than a seven-day supply or the minimum amount needed for proper treatment of the patient until the patient can obtain access to a pharmacy, whichever is less.

(b) Patient admitted to hospital. Subsection (a) of this section applies to a patient who is admitted to a hospital, including a patient:

(1) admitted to:

(A) a general hospital, special hospital, licensed ambulatory surgical center, surgical suite in a dental school, or veterinary medical school; or

(B) a hospital clinic or emergency room, if the clinic or emergency room is under the control, direction, and administration as an integral part of a general or special hospital;

(2) receiving treatment with a Schedule II controlled substance from another person, who is:

(A) a member of a life flight helicopter medical team or an emergency medical ambulance crew or a paramedic-emergency medical technician; and

(B) considered an extension of an emergency room of a general or special hospital; or

(3) receiving treatment with a Schedule II controlled substance while the patient is an inmate incarcerated in a correctional facility operated by the Texas Department of Criminal Justice.

(c) Animal admitted to hospital. Subsection (a) of this section applies to an animal admitted to an animal hospital, including an animal that is a permanent resident of a zoo, wildlife park, exotic game ranch, wildlife management program, or state or federal research facility.

(d) Long-Term Care Facility (LTCF). An official prescription form is not required in a long-term care facility if:

(1) an individual administers the substance to an inpatient from the facility's medical emergency kit;

(2) the individual administering the substance is an authorized practitioner or an agent acting under the practitioner's order; and

(3) the facility maintains the proper records as required for an emergency medical kit in an LTCF.

(e) Therapeutic optometrist. An official prescription form is not required when a therapeutic optometrist administers a topical ocular pharmaceutical agent in compliance with:

(1) the Texas Optometry Act; and

(2) a rule adopted by the Texas Optometry Board under the authority of the Texas Optometry Act.

§13.75. Pharmacy Responsibility--Generally. (a) Upon receipt of a properly completed official prescription form, a dispensing pharmacist must:

(1) ensure that all requirements of Section 481.074(k) have been met;

(2) the date the prescription is presented is not later than 21 days after the date of issuance;

(3) sign the prescription;

(4) enter the date filled and the pharmacy prescription number;

(5) if a triplicate form, indicate on all copies whether the pharmacy dispenses to the patient a quantity less than the quantity prescribed; and

(6) if a triplicate form, enter the following information on all copies, if different from the prescribing practitioner's information:

(A) the brand name or, if none, the generic name of the controlled substance dispensed; or

(B) the strength, quantity, and dosage form of the Schedule II controlled substance used to prepare the mixture or compound.

(b) The prescription is void if presented for filling later than 21 days after issuance, or 21 days after any earliest fill date. A new prescription is required.

§13.76. Pharmacy Responsibility--Electronic Reporting. Within the time required by the Act, a pharmacy must submit the following data elements from Schedule II prescriptions to the director:

(1) the prescribing practitioner's DPS registration number;

(2) the official prescription control number;

(3) the patient's (or the animal owner's) name, age (or date of birth), and address (including city, state, and zip code);

(4) the date the prescription was issued and filled;

(5) the NDC # of the controlled substance dispensed;

(6) the quantity of controlled substance dispensed;

(7) the pharmacy's prescription number; and

(8) the pharmacy's DPS registration number.

§13.77. Electronic Compatibility. If a pharmacy submits information to the director electronically, the pharmacy must submit the information by electronic media, including a disk, tape, cassette, modem, or other manner compatible with industry standards and approved by the director.

§13.78. Waiver from Electronic Reporting. (a) Minimum prescription threshold. If a pharmacy fills less than 15 prescriptions per month, the pharmacy may request from the director a waiver from electronic reporting. If a waiver is granted, the pharmacy must file reportable prescriptions with the director on a form approved under §13.79(c) of this title (relating to Pharmacy Responsibility - Non-electronic Reporting).

(b) Inadequate technology. If a pharmacy is not automated or cannot meet the requirements in §13.77 of this title (relating to Electronic Compatibility), the pharmacy may request from the director a waiver from electronic reporting. The request must clearly describe the technological inadequacies in the pharmacy.

(c) Written request. The waiver must be requested annually in writing.

(d) Duration. If granted, the waiver will remain in effect for no longer than twelve months, beginning the first day of the month following the month the waiver was granted.

§13.79. Pharmacy Responsibility – Non-electronic Reporting. (a) With waiver. A pharmacy must comply with §13.76 of this title (relating to Pharmacy Responsibility - Electronic Reporting) unless the pharmacy has obtained from the director a waiver from electronic reporting under §13.78 of this title (relating to Waiver from Electronic Reporting).

(b) Non-electronic information. Within the time required by the Act, a pharmacy approved for non-electronic reporting under this subchapter must submit the following information to the director on a form approved by the director:

(1) the information required under §13.76 of this title (relating to Pharmacy Responsibility - Electronic Reporting);

(2) the prescribing practitioner's name; and

(3) the dispensing pharmacy's name, address, and telephone number.

(c) Approved forms. The director expressly approves the following non-electronic reporting forms, if the form in question legibly includes all information required by subsection (b) of this section:

(1) Copy 1 of a triplicate prescription form;

(2) a copy of a single official prescription form; and

(3) a printed computer record of the prescription.

§13.80. Pharmacy Responsibility – Emergency Situation. (a) Documentation. If a pharmacy dispenses a Schedule II controlled substance in an emergency situation pursuant to an orally or telephonically communicated prescription from a practitioner or the practitioner's designated agent, the pharmacist must promptly reduce the prescription to writing, including the information required:

(1) by law for a standard prescription; and

(2) by this subchapter for an official prescription.

(b) Other requirements. After dispensing a controlled substance in an emergency under this section, the dispensing pharmacy must, within the time required by the Act:

(1) maintain the written record created under subsection (a) of this section until the pharmacy receives the original official prescription from the practitioner;

(2) note the emergency nature of the prescription;

(3) upon receipt from the practitioner, attach the original official prescription to the orally or telephonically communicated prescription;

(4) retain both documents in the pharmacy records; and

(5) send the information required under this subchapter to the director (Texas Prescription Program).

§13.81. Pharmacy Responsibility – Questionable Prescription. If a dispensing pharmacist receives an official prescription form that creates a substantial question or doubt in the mind of the dispensing pharmacist, the pharmacist must, before filling the prescription, communicate with the prescribing practitioner in order to resolve the question or doubt.

§13.82. Pharmacy Responsibility – Out-of-State Practitioner. (a) If a pharmacist in this state receives a prescription, that is not on an official prescription form, that is for a Schedule II controlled substance, and that is issued by a practitioner in another state, the pharmacy may fill the prescription if:

(1) the practitioner is authorized by the other state to prescribe the substance;

(2) the pharmacy has a plan approved by and on file with the director allowing the activity; and

(3) the pharmacy processes and submits the prescription according to the reporting requirements approved in the plan.

(b) The approval of the plan will run concurrently with the pharmacy's registration.

§13.83. Return of Unused Form. (a) Requirements. An unused official prescription form is invalid and the practitioner or another person acting on behalf of the practitioner must return the unused form to the director (Texas Prescription Program) with an appropriate explanation not later than the 30th day after the date:

(1) the practitioner's license to practice, Texas controlled substances registration number, or DEA number is canceled, revoked, suspended, denied, or surrendered or amended to exclude the handling of all Schedule II controlled substances; or

(2) the practitioner dies.

(b) Institutional practitioner. An individual who is an institutional practitioner must return an unused official prescription form to the administrator of the hospital or other training institution upon completion or termination of the individual's training at the hospital or institution. The administrator must return an unused official prescription form to the director (Texas Prescription Program) not later than the 30th day after the date the individual completes or terminates all training programs.

(c) Licensed practitioner. Except as provided by subsection (d) of this section, no individual may continue to use an official prescription form issued under an institutional practitioner's permit number or similar number after the individual has been properly and individually licensed as a practitioner by the appropriate state health regulatory agency.

(d) Waiver. The director may upon request waive the requirements of subsections (b) and (c) of this section and allow an individual to continue to use an institutional practitioner number under this subchapter after the individual has been licensed as a practitioner by the appropriate state health regulatory agency.

§13.84. Release of Non-statistical Information. (a) To whom. The director may release Texas Prescription Program information obtained under the Act, §481.075 only to an individual listed in the Act, §481.076(a).

(b) Purpose. An individual described by subsection (a) of this section may only request information for a purpose listed in the Act, §481.076.

(c) Written request. The director may require an individual seeking information under this section to submit a written request to the director before the director releases to the individual the information contained on or derived from the prescription.

(d) Proper need and Return of Information report. The director will require a person requesting information under the Act, §481.076(a)(3), to show a proper need for the information. The showing of proper need is ongoing. The director will require the person to periodically submit to the director a Return of Information report documenting use of the information and the status of the investigation or prosecution.

§13.85. Deletion or Return. (a) Generally. Under the authority of the Act, §481.0761(b), the director may determine whether a Schedule II controlled substance should be deleted from or returned to the official prescription program.

(b) Deletions. The director has determined:

(1) the burden imposed by the official prescription program on each controlled substance listed in this subsection substantially outweighs the risk of diversion; and

(2) the following controlled substances are deleted from the program: (none).

(c) Returns. The director has determined:

(1) the burden imposed by the official prescription program on each controlled substance listed in this subsection does not substantially outweigh the risk of diversion; and

(2) the following controlled substances are returned to the program: (none).

13.86. Prescription Forms. (a) Who may utilize form. A practitioner, as defined in the Act, Section 481.002(39)(A), (C), (D), may use prescription forms and order forms through individual sources. If a written prescription form is to be used to prescribe a controlled substance the dispensing practitioner must be registered by the director and the DEA under both state and federal law to prescribe controlled substances.

13.87. Written Form. (a)Use. A practitioner may issue, or permit to be issued, by a person under the practitioner's direction or supervision, a Schedule III-V controlled substance on a prescription form for a valid medical purpose and in the course of medical practice.

(b) Refills permitted. Schedule III – V prescriptions may be refilled up to five times within the six months period after date of issuance.

(c) Completion. A practitioner who prescribes any quantity of a Schedule III- V controlled substance must complete the prescription form by legibly filling in all required information.

(d) Other requirements. A practitioner:

(1) may not postdate a prescription form; and

(2) must ensure all information required in the Act, Section 481.074(k), which includes the department registration number, if licensed in Texas, be included on every prescription[is included and is legible, to include the stamped or pre-printed instructions].

13.88. Exceptions to Use of Written Form. (a) Medication order. A prescription form is not required for a medication order written for a patient who is admitted to a hospital at the time the medication order is written and filled.

(1) A practitioner may dispense or cause to be dispensed a controlled substance to a patient who:

(A) is admitted to the hospital; and

(B) will require an emergency quantity of a controlled substance upon release from the hospital.

(2) Under paragraph (1) of this subsection, the controlled substance:

(A) may only be dispensed in a properly labeled container; and

(B) may be an amount as determined appropriate by the attending practitioner as needed for proper treatment of the patient until the patient can obtain access to a pharmacy.

(b) Patient admitted to hospital. Subsection (a) of this section applies to a patient who is admitted to a hospital, including a patient:

(1) admitted to:

(A) a general hospital, special hospital, licensed ambulatory surgical center, surgical suite in a dental school, or veterinary medical school; or

(B) a hospital clinic or emergency room, if the clinic or emergency room is under the control, direction, and administration as an integral part of a general or special hospital;

(2) receiving treatment with a controlled substance from another person, who is:

(A) a member of a life flight aircraft medical team or an emergency medical ambulance crew or a paramedic-emergency medical technician; and

(B) considered an extension of an emergency room of a general or special hospital; or

(3) receiving treatment with a controlled substance while the patient is an inmate incarcerated in a correctional facility operated by the Texas Department of Criminal Justice.

(c) Animal admitted to hospital. Subsection (a) of this section applies to an animal admitted to an animal hospital, including an animal that is a permanent resident of a zoo, wildlife park, exotic game ranch, wildlife management program, or state or federal research facility.

(d) Long-Term Care Facility (LTCF). A prescription form is not required in a long-term care facility if:

(1) an individual administers the substance to an inpatient from the facility's medical emergency kit;

(2) the individual administering the substance is an authorized practitioner or an agent acting under the practitioner's order; and

(3) the facility maintains the proper records as required for an emergency medical kit in an LTCF.

13.89. Pharmacy Responsibility – Generally. (a) Upon receipt of a properly completed written prescription form or oral, telephonic or electronic prescription, a dispensing pharmacist must:

(1) ensure that all requirements of Section 481.74(k) of the Act have been met;

(2) ensure that the date the prescription is presented is not later than six months after the date of issuance;

(3) ensure that the prescription presented has not been refilled more than five times during the six months period after the date the prescription was issued, unless the prescription is renewed by the practitioner;

(4) enter the date filled and the pharmacy prescription number; and

(5) indicate whether the pharmacy dispenses to the patient a quantity less than quantity prescribed.

(b) The prescription is void if presented for filling later than six months after issuance or has been filled five times during the six months after issuance. A new prescription is required.

13.90. Pharmacy Responsibility – Electronic Reporting. Within the time required by the Act, a pharmacy must submit the following data elements from Schedule III thru V prescriptions to the director:

(1) the prescribing practitioner's DPS registration number, unless the prescription was issued by a practitioner in another state as permitted under Section 13.96 of this title;

(2) the patient's (or the animal owner's) name, age (or date of birth), and address (including city, state, and zip code);

(3) the date the prescription was issued and filled;

(4) the NDC # of the controlled substance dispensed;

(5) the quantity of controlled substance dispensed;

(6) the pharmacy's prescription number; and

(7) the pharmacy’s DPS registration number.

13.91. Electronic Compatibility. If a pharmacy submits information to the director electronically, the pharmacy must submit the information by electronic media, including a disk, tape, cassette, modem, or other manner compatible with industry standards and approval by the director.

13.92. Waiver from Electronic Reporting. (a) Minimum prescription threshold. If a pharmacy fills less than 15 prescriptions per month, the pharmacy may request from the director a waiver from electronic reporting. If a waiver is granted, the pharmacy must file reportable prescriptions with the director on a form approved under Section 13.93(c) of this title (relating to Pharmacy Responsibility - Non-electronic Reporting).

(b) Inadequate technology. If a pharmacy is not automated or cannot meet the requirements in Section 13.91 of this title (relating to Electronic Compatibility), the pharmacy may request from the director a waiver from electronic reporting. The request must clearly describe the technological inadequacies in the pharmacy.

(c) Written request. The waiver must be requested annually in writing.

(d) Duration. If granted, the waiver will remain in effect for no longer than twelve months, beginning the first day of the month following the month the waiver was granted.

13.93. Pharmacy Responsibility – Non-electronic Reporting. (a) With waiver. A pharmacy must comply with Section 13.90 of this title (relating to Pharmacy Responsibility - Electronic Reporting) unless the pharmacy has obtained from the director a waiver from electronic reporting under Section 13.92 of this title (relating to Waiver from Electronic Reporting).

(b) Non-electronic information. Within the time required by the Act, a pharmacy approved for non-electronic reporting under this subchapter must submit the following information to the director on a form approved by the director:

(1) the information required under Section 13.90 of this title;

(2) the prescribing practitioner's name; and

(3) the dispensing pharmacy's name, address, and telephone number.

(c) Approved forms. The director expressly approves the following non-electronic reporting forms, if the form in question legibly includes all information required by subsection (b) of this section:

(1) a copy of a prescription form; and

(2) a printed computer record of the prescription.

13.94. Pharmacy Responsibility – Oral, Telephonic or Electronic Prescriptions. (a) Documentation. If a pharmacy dispenses a Schedule III-V controlled substance[in an emergency situation]pursuant to an orally,[or] telephonically or electronically communicated prescription from a practitioner or the practitioner's designated agent, the pharmacist must promptly reduce the prescription to writing, including the information required by the Act, Section 481.074(k).

(b) Other requirements. After dispensing a controlled substance orally, telephonically or electronically under this section, the dispensing pharmacy must, within the time required by the Act:

(1) maintain the written record created under subsection (a) of this section in the pharmacy records for two years from the date dispensed;

(2) inform the practitioner in[note] the event of an emergency refill[nature] of the prescription; and

(3) send the information required under this subchapter to the director (Texas Prescription Program).

13.95. Pharmacy Responsibility – Questionable Prescriptions. (a) If a dispensing pharmacist receives a written prescription form that creates a substantial question or doubt in the mind of the dispensing pharmacist that concerns requirements of Section 481.074(k) of the Act or the authenticity of the prescription, the pharmacist must, before filling the prescription, communicate with the prescribing practitioner in order to resolve the question or doubt.

(b) The pharmacist must document on the prescription the following information:

(1) Date the change or adding of information was authorized;
(2) The information that was authorized to be added or changed;
(3) Name of the prescribing practitioner granting the authorization; and
(4) Initials of the pharmacist.

13.96. Pharmacy Responsibility – Out-of-State Practitioner. (a) If a pharmacist in this state receives a prescription for a Schedule III-V controlled substance that is issued by a practitioner in another state, the pharmacy may fill the prescription if the practitioner is authorized by the other state to prescribe the substance.

(b) Within the time required by the Act, the pharmacist must submit to the director the data elements required under Section 13.90 of this title (relating to Pharmacy Responsibility-Electronic Reporting).

13.97. Release of Non-statistical Information. (a) To whom. The director may release Texas Prescription Program information obtained under the Act, Section 481.074(q) only to an individual listed in the Act, Section 481.076(a).

(b) Purpose. An individual described by subsection (a) of this section may only request information for a purpose listed in the Act, Section 481.076.

(c) Written request. The director may require an individual seeking information under this section to submit a written request to the director before the director releases to the individual the information contained on or derived from the prescription.

(d) Proper need and Return of Information report. The director will require a person requesting information under the Act, Section 481.076(a)(3), to show a proper need for the information. The showing of proper need is ongoing. The director will require the person to periodically submit to the director a Return of Information report documenting use of the information and the status of the investigation or prosecution.

13.98. Deletion or Return. (a) Generally. Under the authority of the Act, Section 481.0761(b), the director may determine whether a Schedule III, IV or V controlled substance should be deleted from or returned to the prescription program.

(b) Deletions. The director has determined:

(1) the burden imposed by the Texas Prescription Program on each controlled substance listed in this subsection substantially outweighs the risk of diversion; and

(2) the following controlled substances are deleted from the program: (none).

(c) Returns. The director has determined:

(1) the burden imposed by the Texas Prescription Program on each controlled substance listed in this subsection does not substantially outweigh the risk of diversion; and

(2) the following controlled substances are returned to the program: (none).

13.99. Communication with Director (Texas Prescription Program). If a person is required or allowed by this subchapter to make a notification, report, or other written, telephonic, or personal communication to the director, the person must make the communication to the director through the Texas Prescription Program at the address indicated in Section 13.9 of this title (relating to Telephone Number and Address - Texas Prescription Program).

Subchapter E. Precursors and Apparatus

§13.101. Subchapter Definitions. The following words and terms, when used in this subchapter, have the following meanings, unless the context clearly indicates otherwise.

(1) **Annual permit** – A permit issued to a person by the director under this subchapter authorizing the person to receive or deliver a precursor or apparatus for one year from the date of issue or renewal.

(2) **Apparatus** – An item of chemical laboratory equipment covered by this subchapter, that is designed, made, or adapted to manufacture a controlled substance or a controlled substance analogue. This term:

(A) does not include any item expressly deleted from the list of apparatus in §13.116 of this title (relating to Additions or Deletions) after being determined by the director to no longer jeopardize public health and welfare by evidenced proliferation or use in clandestine laboratories or other illicit manufacturer of a controlled substance or controlled substance analogue; and

(B) includes, except as provided by subparagraph (A) of this paragraph:

(i) any item listed under the Act, §481.080(a); and

(ii) any additional items expressly named to the list in §13.116 of this title (relating to Additions or Deletions) after being determined by the director to jeopardize public health and welfare by evidenced proliferation or use in clandestine laboratories or other illicit manufacturer of a controlled substance or controlled substance analogue.

(3) **Clandestine laboratory** – An illicit chemical laboratory or similar operation consisting of a sufficient combination of precursor and apparatus items used or usable in the illicit manufacture or synthesis of a controlled substance or a controlled substance analogue.

(4) **Deliver** – T o sell, transfer, or otherwise furnish a precursor or apparatus. The term includes taking an order to furnish a precursor or apparatus.

(5) **Distributor** – A manufacturer, wholesaler, broker, repacker, jobber, association, corporation, partnership, or a person who sells, transfers, or otherwise furnishes a precursor or apparatus.

(6) **Legitimately established business or Business** – A business that conforms to all recognized and accepted principles, standards, rules, and laws governing the activities of manufacturing, purchasing, selling, trading, or otherwise lawfully dealing with commodities. While the business engages in such activities, the term includes an individual, corporation, government, business trust, estate, trust, partnership, association, or other legal entity.

(7) **Located in this state** – The person or the person's business office:

(A) is physically located in Texas;

(B) maintains a Texas mailing address for business conduct relating to a precursor or apparatus;

(C) processes or fills orders from a warehouse, branch office, or other site physically located in Texas; or

(D) takes an order using an employee or agent who is physically located in Texas at the time the order is taken.

(8) **NAR-22** – A DPS Form NAR-22 furnished by the director and used to report a transaction under this subchapter.

(9) **One-time permit** – A permit issued by the director to a person authorizing a single receipt or distribution of a precursor or apparatus.

(10) **Otherwise furnish** – To initiate a transaction resulting or intending to result in the receipt or distribution of a precursor or apparatus to a person in this state, regardless of whether the person initiating the transaction is the owner or possessor of the item or merely a broker.

(11) **Permit application** – A form obtained from the director (PCLAS) and submitted by a person seeking a one-time or annual permit to receive or deliver a precursor or apparatus under this subchapter.

(12) **Precursor or chemical precursor** – A chemical substance item covered by this subchapter and commonly used in the illicit manufacture of a controlled substance or a controlled substance analogue.

(A) The term includes:

(i) a chemical precursor listed under the Act, §481.002(51); and

(ii) any additional items expressly named to the list in §13.116 of this title (relating to Additions or Deletions) after being determined by the director to jeopardize public health and welfare by evidenced proliferation or use in clandestine laboratories or other illicit manufacturer of a controlled substance or controlled substance analogue.

(B) The term does not include:

(i) any item expressly deleted from the list of precursors in §13.116 of this title (relating to Additions and Deletions) after being determined by the director to no longer jeopardize public health and welfare by evidenced proliferation or use in clandestine laboratories or other illicit manufacturer of a controlled substance or controlled substance analogue; or

(ii) an immediate precursor under §13.117 of this title (relating to Immediate Precursor List).

(13) **Recipient** – A person who receives, orders, or otherwise seeks to receive a precursor or apparatus, whether through purchase, lease, loan, gift, or other transfer.

(14) **Waiting period** – The 21-day period required before a person may lawfully receive or deliver a precursor or apparatus under the Act, §481.077(f) or §481.080(g).

(15) **Immediate precursor** – A chemical substance item listed in §13.117 of this title (relating to Immediate Precursor List).

(16) **Wholesale distributor** – A distributor who sells, transfers, or otherwise furnishes a product containing ephedrine, pseudoephedrine, or norpseudoephedrine to a retailer.

(17) **Suspicious quantity order** – The circumstances of the sale or transfer of a product containing ephedrine, pseudoephedrine, or norpseudoephedrine would lead a reasonable person to believe the substance is likely to be used for the purpose of unlawfully manufacturing a controlled substance due to any of the following:

(A) the method of payment;

(B) the method of requested delivery;

(C) the amount greatly exceeds previous orders;

(D) the amount exceeds the threshold as set by the United States Drug Enforcement Administration; or

(E) any other circumstance that the wholesale distributor determines to be suspicious.

§13.102. Who Must Obtain Permit. (a) Generally. Except as provided by subsections (c) or (d) of this section, a person must obtain a permit from the director (PCLAS), if the person is physically located:

(1) inside this state and the person:

(A) takes an order from or delivers a precursor or apparatus to another person who is required under this section to obtain a permit to receive the item or to observe the 21-day waiting period under this subchapter;

(B) receives a precursor or apparatus from another person who is located inside or outside this state; or

(C) places an order to purchase a precursor or apparatus even if the person will be physically located outside this state when the sale is completed or the item is received; or

(2) outside this state when an order is placed if the person will be physically located in this state when the sale is completed or the item is received.

(b) Types of permits. Under this subchapter, the director may issue:

(1) a one-time permit to a business or individual; or

(2) an annual permit to a legitimately established business.

(c) Voluntary submission to permitting. No person is required to obtain a permit under this subchapter, if the person is described by §13.103 of this title (relating to Permit Exception). Even if the person is not required to obtain a permit under this subchapter, the director may issue a permit to a person who qualifies and voluntarily applies for the permit. If the person voluntarily obtains a permit, this chapter applies to the person as long as the person holds the permit.

(d) Distribution to a school. A school district or public or private institution of higher education is excepted from the permit requirements of the Act. A private school is not excepted and must comply with the Act and this subchapter. A distributor, who takes an order from or delivers a precursor or apparatus to an excepted school district or institution, must comply with §13.110(h) - (j) of this title (relating to NAR-22). The distributor is not required to:

(1) obtain a distributor permit for that transaction;

(2) observe the 21-day waiting period before completing the transaction;

(3) obtain a permit or letter of authorization from the excepted recipient before completing the transaction; or

(4) report the transaction to the director.

(e) Separate permit for separate location. An applicant who represents a business must make a separate application and obtain a separate permit for each principal place of business.

(f) Distribution to a business. If a business entity described by this subsection does not have a permit, a distributor may lawfully deliver the item to the business without a permit, but only after complying with all other provisions of this subchapter, including a letter of authorization under §13.107 of this title (relating to Business Letter of Authorization) and observation of the 21-day waiting period under §13.108 of this title (relating to Waiting Period).

§13.103. Permit Exception. The director declares by rule a person to be excepted from the permit requirements with respect to a precursor or apparatus covered by this subchapter, if the person:

(1) is excepted from the permit requirements under the Act, §481.0621 or §481.077(l);

(2) is a controlled substances registrant under the authority of the Act, §481.077(c) or §481.080(d);

(3) is a peace officer, who is in the actual discharge of official duties;

(4) is an officer or employee of a federal, state, or local governmental entity, who receives or delivers the item while acting in the usual course of the person's duty, business, or employment;

(5) is a common or contract carrier, a warehouseman, or an employee of a carrier or warehouseman whose possession of the precursor or apparatus is in the usual course of business or employment;

(6) has a valid letter of authorization for the item under §13.107 of this title (relating to Business Letter of Authorization);

(7) receives or delivers the item only in the usual course of business and within a single corporation or other legitimately established business entity for which consent to inspect has been given under §13.104 of this title (relating to Requirements for Permit Issuance);

(8) is an employee acting on behalf of a legitimately established business and under a permit or letter of authorization of a distributor or recipient;

(9) is a distributor located outside this state, without regard to whether the recipient is located inside or outside this state; or

(10) is a recipient who places an order to receive and receives the precursor or apparatus while located outside this state.

§13.104. Requirements for Permit Issuance. (a) One time. The director will issue a one-time permit to distribute or receive a stated precursor or apparatus to a person who:

(1) submits a properly completed permit application;

(2) would not be subject to denial of an application for controlled substances registration under the separate standards for denial found in the Act, §481.063(e);

(3) demonstrates the item will be used solely for legitimate purposes;

(4) complies with federal, state, and local environmental protection, fire, or other related health and safety standards; and

(5) delivers to the director an appropriate written consent described in §13.237 of this title (relating to Inspection of Permit Holder and Pseudoephedrine Records and Reports).

(b) Waiver. The director may waive the requirements of subsection (a)(2) of this section based upon the circumstances surrounding the conviction or supervision described in the Act, §481.063(e)(2), after considering the factors described in the Texas Occupations Code, Chapter 53.

(c) Annual. The director will issue an annual permit to an applicant to receive or deliver a precursor or apparatus if the applicant:

(1) meets each one-time permit requirement; and

(2) represents a legitimately established business.

§13.105. Permit Application. (a) Requirements. A person who seeks a permit under this subchapter must comply with this section and Subchapter F of this chapter (relating to Applications).

(b) Source. An applicant may obtain a form for an original permit application by writing the director (PCLAS). An applicant must make a new or original application for:

(1) a one-time permit on a DPS Form NAR-120; or

(2) an annual permit on a DPS Form NAR-121;

(c) Expiration of annual permit. Except as provided by subsection (d) of this section, a permit document expires after one year from the month of issuance. A permit may indicate the expiration date.

(d) Extension. The director may extend a permit for a period of less than 12 additional months, if the director determines the extension is necessary to evenly allocate the expiration dates of all permits.

(e) Effect of modification or renewal. Except as provided by subsection (d) of this section, modification of a permit or early renewal does not affect the current or future date of expiration.

(f) Effect of expiration. After expiration, the former permit provides the permit holder with no authority to receive or deliver a precursor or apparatus.

(g) Grace period. After expiration under this section, a former permit holder may apply for a new permit. During a six-month grace period after expiration and before termination under subsection (h) of this section, the director (PCLAS) may reserve the original permit number in the name of the original applicant.

(h) Termination. A permit terminates:

(1) at the end of a grace period of six months allowed by the director after expiration; or

(2) if the permit holder is a legitimately established business, when the business ceases legal existence or discontinues business practice. The director will presume that a distributor has discontinued business practice under this subsection if the business has not submitted a NAR-22 reporting a sale or other delivery for two years or more.

(i) New permit required after termination. After termination, a former permit holder must apply for a new permit and may be issued a different permit number.

(j) Effect of termination. After termination, the former permit provides the permit holder with no authority to receive or deliver a precursor or apparatus.

(k) Discontinued activity. If the permit holder is a legitimately established business and discontinues business practice, the permit holder or a representative of the holder must notify the director through the PCLAS by close of business. The director may immediately terminate the permit of a person reported to the director under this subsection.

(l) No fee. There is no application or issuance fee for a permit issued under this subchapter.

§13.106. Permit Document. (a) Issuance. The director will issue a permit document to an applicant who qualifies under the applicable provisions of the Act, Subchapter C, and this subchapter.

(b) NAR-97, one-time. The director will issue a one-time permit on DPS Form NAR-97, containing:

(1) the name, address, identification information, and control number of the permit; and

(2) the activity authorized by the permit.

(c) NAR-94, annual. The director will issue an annual permit on DPS Form NAR-94, containing:

(1) the name, address, and number of the permit;

(2) any limitation on precursor or apparatus activity authorized under the permit; and

(3) the expiration date of the permit.

(d) Display. The permit holder must:

(1) maintain the permit document so the person may promptly retrieve and display it at any time upon proper demand; and

(2) not display the document at the physical location of the person's principal place of business.

(e) A one-time permit is only valid for:

(1) a single transaction; or

(2) one year from the day of issuance, whichever is less.

(f) Transfer. A permit holder may not transfer or assign to another person a permit document or number or an authority conferred by the permit.

§13.107. Business Letter of Authorization. (a) Permit alternative. In lieu of a permit authorizing immediate distribution, a legitimately established business may receive a precursor or apparatus from a distributor within this state after a 21-day waiting period by presenting or providing to the distributor a letter of authorization from the business.

(b) Contents. A letter of authorization from a business recipient must include:

(1) the information required under the Act, §481.077(d)(2)(A) or §481.080(e)(2)(A);

(2) the precursor or apparatus sought;

(3) the name of business issuing the letter;

(4) the issue date of the letter;

(5) the mailing and physical address, including the number and street name, city, state, and zip code; and

(6) the signature of the individual executing the letter on behalf of the business.

(c) Ordering. A business recipient must provide a letter of authorization to the distributor, if the business orders a precursor or apparatus through an automated ordering system without a permit.

(d) Constructive compliance. If a prospective business recipient submits a purchase order or purchase voucher to a distributor, the director will deem the order or voucher to be sufficient as a letter of authorization if:

(1) it contains the information required in subsection (b) of this section; and

(2) the distributor retains the order or voucher on file.

(e) Expiration. A letter of authorization expires one year from the date of issue.

(f) Retention. The distributor must retain the original letter of authorization on file and forward a copy of the letter, along with a NAR-22 or other communication adequately detailing the proposed transaction, to the director (PCLAS). Until expiration, a distributor may use the original for future distributions. The recipient must issue a new letter:

(1) after the letter expires; or

(2) if material information required in the original letter changes.

§13.108. Waiting Period. (a) 21 days, generally. The Act requires a 21-day waiting period for a precursor or apparatus transfer. Except as provided by this subchapter, a distributor may not deliver a precursor or apparatus before the required waiting period has passed.

(b) Timing of delivery. If a recipient has met the exception, permit, or letter of authorization requirements of this subchapter, a distributor may deliver a precursor or apparatus:

(1) after the required 21-day waiting period has elapsed, if the distributor has submitted the required report of the prospective transaction to the director (PCLAS); or

(2) before the otherwise required waiting period has elapsed, if the director issues a permit.

(c) Permit alternative. A valid one-time or annual permit allows a distributor to complete the transaction before the required 21-day waiting period has elapsed, if:

(1) the prospective recipient presents proper identification to the distributor under §13.110 of this title (relating to NAR-22); and

(2) the permit contains no apparent alterations, if it is a one-time permit; or

(3) the recipient furnishes to the distributor the permit number, if it is an annual permit.

(d) Beginning date. Except as provided by this subsection, the 21-day waiting period begins on the date the director receives a copy of the letter of authorization. If the distributor mails the letter of authorization to the director (PCLAS) and the director receives the letter of authorization more than three days after it was postmarked, the 21-day waiting period begins three days after the date the distributor's letter was postmarked.

§13.109. Reporting Distribution. (a) Generally. Except as provided by this section, a distributor must use a NAR-22 to report to the director (PCLAS) each incident in which the distributor delivers a precursor or apparatus to a person located inside this state. A distributor, who is located in this state and who delivers a precursor or apparatus to a person located inside this state, must report the transaction to the director (PCLAS), whether or not the recipient holds a permit issued under this subchapter.

(b) Business without permit. A distributor, who seeks to deliver a precursor or apparatus to a legitimately established business, that does not have a permit and is not excepted from the permit requirements of the Act or this subchapter, must report the proposed transfer to the director. The report must include a copy of the letter of authorization, along with a NAR-22 or other communication adequately detailing the proposed transaction, and must be transmitted to the director (PCLAS). The distributor may lawfully deliver the item only after observing the 21-day waiting period under §13.108 of this title (relating to Waiting Period).

(c) Time. Except as provided by subsections (d) through (i) of this section, the report must be made not later than the seventh day after the distributor completes the transaction.

(d) Comprehensive monthly report. The director may authorize a distributor to make a comprehensive monthly report of transactions covered by this section. If authorized to make a monthly report, the distributor:

(1) must make the report to the director (PCLAS); and

(2) may make the report on:

(A) one or more complete NAR-22 forms, that are submitted at one time under this section and that contain all information required for each relevant transaction with a particular individual recipient; or

(B) a single, complete NAR-22 with the total monthly information clearly tabulating all relevant transactions with a particular recipient.

(e) Copy of one-time permit. When making a comprehensive monthly report, a distributor must attach the original copy (Copy 1) of each one-time permit to the original copy (Copy 1) of the NAR-22. A comprehensive monthly report is due on the 30th day after the end of the month covered by the report and may be submitted earlier.

(f) Computer report. A distributor may make the comprehensive monthly report by submitting a computer-generated report, if:

(1) the director (PCLAS):

(A) receives a request to approve monthly reports at least 30 days before the first month for which approval is sought;

(B) authorizes the computer-generated report; and

(C) approves the method of reporting, including:

(i) hard copy;

(ii) magnetic tape;

(iii) PC compatible diskette; or

(iv) other similar, compatible method; and

(2) the information contained in the report is in the same order and completeness as it appears in the applicable parts of the NAR-22.

(g) Accuracy. The distributor:

(1) is responsible for the accuracy of the computer-generated report; and

(2) must promptly correct a data entry or transmission error.

(h) Rescission. The director may rescind authorization to use computer-generated reports with 30 days notice to the distributor.

(i) Demand letter. If the director determines a manufacturer or wholesaler has failed to comply with subsections (d) through (g) of this section, the director may send a demand letter to the business. The director will send the letter certified mail, return receipt requested. The letter may:

(1) require:

(A) the business to provide the director all or part of the information required by statute and this subchapter not later than the 30th day after the date the director mailed the demand letter;

(B) submission of all or part of the information maintained for the past two-year period; or

(C) strict compliance with the reporting requirements of this subchapter for a stated period of time; and

(2) find that, for a stated period of time, subsections (d) through (f) of this section do not apply to the business.

§13.110. NAR-22. (a) Generally. The NAR-22 contains information required from a distributor to describe the relevant details of the transaction, including information about a recipient of a precursor or apparatus.

(b) Format. The distributor must complete all applicable sections of the NAR-22.

(c) Presentation. A prospective recipient must present an original one-time permit to the distributor, so the distributor can complete the information required under this section. A copy or an electronic transmission of a one-time permit is not sufficient under this subsection. The prospective recipient may present the permit in person or by mail before or at the time of distribution.

(d) ID source. The distributor must obtain the information required to identify a recipient under a one-time permit from information observed by the distributor on a:

(1) state driver license or state issued identification card physically presented by the recipient; or

(2) copy of a state driver license or state issued identification card mailed or electronically transmitted by the recipient.

(e) Ensure ID. A distributor must take reasonable steps to ensure proper identification of a potential recipient, if the prospective recipient holds:

(1) a one-time permit and:

(A) presents the documents in person, the distributor must compare the picture on the driver license or identification card with the physical appearance of the individual prospective recipient; or

(B) mails or electronically transmits the documents, the distributor must compare information on the copy of the license or card with the relevant information on the permit.

(2) an annual permit and:

(A) presents the identification documents in person, the distributor must compare the picture on the driver license or identification card with the physical appearance of the individual prospective recipient; or

(B) mails or electronically transmits the identification documents, the distributor must compare information on the copy of the license or card with the relevant information on the permit.

(f) Constructive compliance. The director will deem a distributor to be in compliance with subsection (e) of this section if the information on the one-time permit and the license or card is essentially the same and the distributor compared and matched the name, date of birth, home address, and license or card number.

(g) Vehicle information. If the recipient owns or operates a motor vehicle that is used during the transaction, the distributor must record the year, state, and number of the vehicle license plate displayed on the vehicle.

(h) Exception claimed. A distributor may not complete a transaction with a person claiming an exception until the distributor has complied with this section.

(i) Proof of exception required. If a potential recipient claims an exception under the Act or these rules, the distributor must obtain the information required to identify the recipient claiming the exception in the same manner as required under subsections (d) through (g) of this section. If an employee or representative of an excepted agency places an order:

(1) in person, the distributor must request the employee or representative to display, present, or provide to the distributor:

(A) proof of agency employment by displaying agency identification;

(B) the name and telephone number of the individual's supervisor to contact in order to verify employment;

(C) a controlled substances registration number; or

(D) other reasonable proof that the Act or this subchapter does not apply to the individual or to the particular transaction; or

(2) by mail or otherwise without appearing in person, the distributor must take reasonable steps to ensure that the claim is legitimate including, for example, an order placed on agency letterhead to be mailed to an agency address.

(j) Unless the distributor is familiar with the person claiming the exception, the distributor must take reasonable steps to verify the claim by contacting the business, agency, or supervisor provided to the distributor under subsection (i) of this section.

§13.111. Exclusion. This subchapter does not apply to the sale or transfer of any compound, mixture, or preparation containing ephedrine, pseudoephedrine, or norpseudoephedrine that is in liquid, liquid capsule, or liquid gel capsule form and is:

(1) mixed or combined with another noncontrolled chemical or substance in the manufacture of a substance;

(2) used for a legitimate purpose; and

(3) only reclaimable through a distillation or extraction process.

§13.112. Ephedrine, Pseudoephedrine, and Norpseudoephedrine. (a) Generally. A wholesale distributor who sells, transfers, or otherwise furnishes a product containing ephedrine, pseudoephedrine, or norpseudoephedrine to a retailer shall obtain before delivering the product:

(1) the retailer's business name, address, area code, and telephone number;

(2) the name of the person making the purchase;

(3) the amount of the product containing ephedrine, pseudoephedrine, or norpseudoephedrine ordered; and

(4) any other information that may be required by the director.

(b) Record. A wholesale distributor shall make an accurate and legible record of the information in subsection (a) of this section and the amount of the product containing ephedrine, pseudoephedrine, or norpseudoephedrine actually delivered. A wholesale distributor shall retain the record for a period of at least two years after the date of the transaction. The record shall be made available to the director upon request.

(c) Suspicious Quantity Report. Not later than 10 business days after the receipt of an order for a product containing ephedrine, pseudoephedrine, or norpseudoephedrine that requests delivery of a suspicious quantity of that product, a wholesale distributor shall submit a NAR-91B (Report of Theft, Loss or Suspicious Order of Precursor Chemical/Laboratory Apparatus) to the director as a report of the suspicious order. The NAR-91B is available on the department website at www.txdps.state.tx.us.

(d) Failure to Report. A wholesale distributor who, with reckless disregard for the duty to report, fails to report as required by subsection (c) of this section shall be subject to disciplinary action to include:

(1) denial, suspension, or revocation of any permit or registration issued by the department;

(2) notification to the Texas Department of State Health Services; and

(3) notification to the United States Drug Enforcement Administration.

§13.113. Out-of-State Activity. (a) Distributor. Except as required by this section, a distributor who is located outside this state may distribute without complying with this subchapter. A distributor who is located in this state must meet:

(1) the permit requirements of §13.102 of this title (relating to Who Must Obtain Permit); and

(2) the reporting requirements of §13.109 of this title (relating to Reporting Distribution).

(b) Recipient. If the recipient is located outside this state at the time of order and at the time of receipt, this subchapter does not apply and the distributor need not require a permit or a letter of authorization from the recipient.

§13.114. Security, Record Keeping, Inventory, Inspection, and Reporting Discrepancy, Loss, Theft, or Diversion. A distributor, wholesale distributor, or recipient must comply with the applicable provisions of:

(1) Subchapter H of this chapter (relating to Security);

(2) Subchapter I of this chapter (relating to Record Keeping);

(3) Subchapter J of this chapter (relating to Inventory);

(4) Subchapter K of this chapter (relating to Inspection); and

(5) Subchapter L of this chapter (relating to Reporting Discrepancy, Loss, Theft, or Diversion).

§13.115. Communications with Director (PCLAS). If a person is required or allowed by this subchapter to make a notification, report, or other written, telephonic, or personal communication to the director, the person must make the communication to the director through the PCLAS at the address indicated in §13.10 of this title (relating to Telephone Number and Address - Precursor Chemical/Laboratory Apparatus Section).

§13.116. Additions or Deletions. (a) Generally. Under the authority of the Act, §481.077(b) and §481.080(c), the director may determine a precursor or apparatus should be added to or deleted from the precursor or apparatus lists.

(b) Precursor additions. The director has determined:

(1) each chemical precursor substance listed in this subsection does jeopardize public health and welfare and is proliferating or being used in clandestine laboratories or other illicit manufacture of a controlled substance or controlled substance analogue; and

(2) each of the following items are named to the list of chemical precursor substances subject to the Act, §481.077(b): red phosphorus and hypophosphorous acid.

(c) Precursor deletions. The director has determined:

(1) each chemical precursor substance listed in this subsection does not jeopardize public health and welfare and is not proliferating or being used in clandestine laboratories or other illicit manufacture of a controlled substance or controlled substance analogue; and

(2) each of the following items are deleted from the list of chemical precursor substances subject to the Act, §481.077(b): (none).

(d) Apparatus additions. The director has determined:

(1) each item of chemical laboratory apparatus listed in this subsection does jeopardize public health and welfare and is proliferating or being used in clandestine laboratories or other illicit manufacture of a controlled substance or controlled substance analogue; and

(2) each of the following items are named to the list of items of chemical laboratory apparatus subject to the Act, §481.080(a): (none).

(e) Apparatus deletions. The director has determined:

(1) each item of chemical laboratory apparatus listed in this subsection does not jeopardize public health and welfare and is not proliferating or being used in clandestine laboratories or other illicit manufacture of a controlled substance or controlled substance analogue; and

(2) each of the following items are deleted from the list of items of chemical laboratory apparatus subject to the Act, §481.080(a): (none).

§13.117. Immediate Precursor List. The following substances are designated as being an immediate precursor as provided under the Act, §481.002(22):

(1) Benzaldehyde;

(2) Gamma-Butyrolactone (other names include: GBL; Dihydro-2(3H)-furanone; 1,2-Butanolide; 1,4-Butanolide; 4-Hydroxybutanoic acid lactone; gamma-hydroxybutyric acid lactone);

(3) Isosafrole;

(4) 3,4-Methylenedioxyphenyl-2propanone;

(5) N-Methylephedrine, its salts, optical isomers, and salts of optical isomers;

(6) N-Methylpseudoephedrine, its salts, optical isomers, and salts of optical isomers;

(7) Piperonal;

(8) Safrole; and

(9) Lithium metal removed from a battery and immersed in kerosene, mineral spirits, or similar liquid that prevents or retards hydration.

Subchapter F. Application

§13.131. Subchapter Definitions. The following words and terms, when used in this subchapter, have the following meanings, unless the context clearly indicates otherwise.

(1) **Registrant** –A person who holds a registration or permit covered by this chapter.

(2) **Registration** – A registration issued under this chapter, including a general controlled substances registration, a TCSR, a specific peyote distributor registration, or a precursor or apparatus permit issued under this chapter.

§13.132. Application Requirements. (a) Time. A person who is required or allowed to register and who is not so registered may apply for registration at any time. A person who is currently registered may not apply for renewal of registration more than 60 days before the expiration date of the current registration.

(b) Form and content, generally. A person must make application for an original registration or renewal of registration on a form provided by the director and submitted to the director through the appropriate section of the Narcotics Regulation Bureau. An application must contain all information called for, unless:

(1) the information is not applicable; and

(2) the applicant expressly so states on the application.

(c) Applicant responsibility. The applicant is responsible for the application. If the director has not sent a form to or received a form from the applicant, this does not relieve the applicant from responsibility for:

(1) being registered or permitted;

(2) making a timely, complete application;

(3) paying the applicable fee; and

(4) updating any information as required by §13.208 of this title (relating to Requirement to Update Information) including each change of a temporary Texas business address by a Locum Tenen or Health Practitioner.

(d) Signature. This subsection and subsection (e) of this section do not apply to a permit application. Except as provided by subsection (e) of this section, one of the following individuals must sign an application form and each additional document or statement required by the director:

(1) the applicant, if the applicant is an individual;

(2) a general partner of the applicant, if the applicant is a partnership;

(3) an officer of the applicant, if the applicant is a corporation or other business association;

(4) the administrator of the applicant, if the applicant is a hospital or teaching institution; or

(5) the pharmacist-in-charge of the applicant, if the applicant is a pharmacy or a remote site.

(e) Alternative signature. If an individual is not listed in subsection (d) of this section, an applicant who is listed may authorize the individual to sign an application form or other document on the applicant's behalf by filing a power of attorney. The applicant must:

(1) ensure that the power of attorney is signed by an individual who is listed in subsection (d) of this section; and

(2) file the power of attorney with the director (CSR Section).

(f) Rejectable signature. The director may reject an application if a signature required by this chapter is incomplete or insufficient, including a signature accompanied by a notation that the signature is "reserved," "without prejudice," "locus sigilli," "L. S.," or otherwise apparently less than fully effective for the required purpose.

(g) Mid-level practitioners.

(1) each mid-level practitioner must have a supervisory physician delegating prescriptive authority as required by the Act, §481.002(39)(D). Each physician must certify the authorizing delegation on the mid-level practitioner's application and include the physician's:

(A) name;

(B) Texas Medical Board license number;

(C) DPS registration number;

(D) signature; and

(E) date of signature.

(2) Effect of signature. A physician who signs a mid-level practitioner's application as the supervising physician assumes responsibility for ensuring that the mid-level practitioner practices under the laws of this state related to controlled substances prescribing activities. A physician who fails to properly monitor the mid-level practitioner's activities is subject to disciplinary action.

(3) Registration and License Status. A supervising physician must have an unrestricted and active DPS registration and Texas Medical Board license number.

(4) Change of Delegating Physician.

(A) A change of delegating physician must be submitted in writing as required in §13.208 of this title (relating to Requirements to Update Information).

(B) A delegating physician shall notify the director in writing to terminate delegation with a mid-level practitioner.

(5) A physician who holds the position of Medical Director, Chief of Staff, or Emergency Room Department Chair at a licensed hospital may be denoted as the supervising physician for a mid-level practitioner providing medical services within the emergency room.

This physician may then delegate the direct supervision of the mid-level practitioner to staff physicians providing medical services within the emergency room, provided that the supervising physician determines that the mid-level practitioners are properly trained to deliver services, that the services are of such a nature that they may be safely and competently delivered by the supervised mid-level practitioners, and that the proper paperwork has been filed with the Texas Medical Board. The supervision of mid-level practitioners must comply with all institutional rules and there must be accurate and timely internal institutional records, which are available upon request within 24 hours to the Department, which list the name and license number of the physician.

(6) Limitations. The physician is limited to the extent and number of mid-level practitioners that the physician delegated as outlined in Chapter 157, Occupations Code.

(h) EMSP. An application from an EMSP seeking to register EMS or FRO activities must be signed by an executive of the EMSP and the EMSMD.

§13.133. Application Form and Content. (a) Request. An applicant may request an application for registration or renewal from the director.

(b) Form. An applicant must make a new, original, or renewal application on the form required by this chapter.

(c) Renewal. The director will mail a form for an application for renewal to a registrant approximately 60 days before the expiration date of the registration to the address currently on file with the appropriate section of the Narcotics Regulation Bureau.

(d) Applicant responsibility. A person should promptly notify the director through the appropriate section of the Narcotics Service if the person is a:

(1) controlled substances or peyote distributor registrant, who does not receive a renewal form within 30 days before the expiration date of the registration; or

(2) permit holder, who does not receive a renewal form within seven days before the expiration date of the registration.

(e) A CSR registrant must sign a consent to inspect under the Act, §481.063(a).

§13.134. Acceptance for Filing. (a) Date received. The director will note the date the director receives an application submitted to the appropriate section of the Narcotics Regulation Bureau for filing.

(b) Acceptance. If the director determines the application is complete, the director will accept the application for filing. The director will not generally accept an application that fails to comply with this subchapter. In the case of a minor defect as to completeness, the director may accept the application for filing and ask the applicant to submit additional information to remedy the defect.

(c) Rejection. Not later than the 60th day after the date the director receives a defective application for filing, the director will mail written notice to the applicant rejecting the application and informing the applicant of its deficiency. The director will return a defective application to the applicant along with notice of the reason for rejecting the application for filing. An applicant may correct a rejected or defective application and resubmit it for filing at any time, if a new registration is being sought.

(d) Time limit. Not later than the 60th day after the date the director accepts an application for filing, the director will determine whether to deny or issue the registration.

(e) Multiple registrations. Although a person attempting to obtain or renew more than one registration may submit all of the registration applications in one package, an individual application must contain all the information called for on the individual form. No application may refer to another application for required information.

(f) Neutral effect of acceptance. The fact the director has accepted an application for filing does not mean the director will grant the application.

(g) Review. The director will review an application for registration and other information gathered during the inspection regarding the applicant in order to determine whether the applicant meets the relevant standards of this chapter and the Act, Subchapter C.

§13.135. Additional Information. (a) May be required. If additional information is necessary to determine whether to issue or renew the application, the director may require an applicant to submit a document or written statement of fact relevant to the application.

(b) Failure to provide. If an applicant fails to furnish a document or statement within 60 days after being requested to do so by the director, the director will deem the failure to be a waiver by the applicant of an opportunity to present the information for consideration by the director in the matter.

§13.136. Amendment or Withdrawal of Application. (a) Written request. An applicant may amend or withdraw an application without the permission of the director by submitting a written request to the director through the appropriate section of the Narcotics Service.

(b) Constructive withdrawal. After an application has been accepted for filing, the director will deem it withdrawn if:

(1) the applicant makes a request for withdrawal or return; or

(2) the applicant fails to respond within 60 days to official correspondence regarding the application.

§13.137. Modification. (a) Availability. A registrant may apply to the director through the appropriate section of the Narcotics Regulation Bureau for registration modification to:

(1) authorize the addition or deletion of a schedule, precursor, or apparatus;

(2) change any information on the name line of the registration;

(3) correct, at the discretion of the director, other information on the registration certificate or permit document; or

(4) change a supervising physician delegating prescriptive authority to include the physician's:

(A) name;

(B) Texas Medical Board license number;

(C) DPS registration number;

(D) signature; and

(E) date of signature.

(b) Written request. A person must notify the director in writing of the modification sought, including the signature of the registrant or other person who is authorized to sign an original application under §13.132(d) or (e) of this title (relating to Application Requirements).

(c) Denial. A modification of registration can be denied if the modification does not meet the requirements under this section or if the registrant violates a ground of denial as described in the Act, Section 481.063(e).

Subchapter G. Forfeiture and Destruction

§13.151. Subchapter Definitions. The following words and terms, when used in this subchapter, have the following meanings, unless the context clearly indicates otherwise.

(1) **Abusable glue and aerosol paint** – Has the meaning given that term by the Texas Health and Safety Code, Chapter 485.

(2) **Excess quantity** – Unless otherwise modified under §13.157(d) of this title (relating to SOP for Destruction By Laboratory or Agency--Security Control), more than:

(A) two kilograms of bulk dry evidence, such as powder;

(B) 500 milliliters of bulk liquid evidence, such as a chemical precursor or liquid controlled substance;

(C) 200 dosage or abuse units of an item, such as tablets, capsules, liquids, or other items so measured;

(D) 50 pounds of bulk packaged marihuana;

(E) five individual controlled substance plants, such as marihuana or peyote; or

(F) five miscellaneous items of drug or inhalant paraphernalia.

(3) **Hazardous material** – An item that:

(A) creates a health or environmental hazard or prohibits safe storage because of its nature and quantity; or

(B) meets the hazardous waste criteria of the United States Environmental Protection Agency (EPA), because of its nature, including its corrosivity, ignitability, reactivity, toxicity, or other hazardous characteristic.

(4) **Item** – Controlled substance property, controlled substance plant, simulated controlled substance, volatile chemical or related inhalant paraphernalia, or abusable glue, aerosol paint, or related inhalant paraphernalia, as those terms are used in the Texas Health and Safety Code, Chapters 481 - 485.

(5) **Laboratory** – A crime laboratory located in this state that holds a registration number for the analysis of a controlled substance from the director and DEA.

(6) **Lawful possession** – Includes the possession of an item obtained in accordance with state or federal law.

(7) **Simulated controlled substance** – Has the meaning given that term by the Texas Health and Safety Code, Chapter 482.

(8) **SOP** – A standard operation procedure established under this subchapter.

(9) **Volatile chemical**--Has the meaning given that term by the Texas Health and Safety Code, Chapter 484.

§13.152. Summary Forfeiture. (a) Generally. An item may be forfeited to the state under this subchapter if:

(1) the lawful possession of the item cannot be readily ascertained; and

(2) the law enforcement agency or peace officer seizing the item makes every reasonable effort to investigate lawful possession.

(b) Forfeiture requirements. Except as provided in subsection (c) of this section, an item is summarily forfeited to the state under this subchapter, if the item is of a type commonly abused and:

(1) an apparently legitimate possessor has voluntarily surrendered the item to a laboratory, law enforcement agency, or peace officer for the express purpose of destruction;

(2) no known lawful possessor can be determined; or

(3) no lawful possessor is reasonably likely to be located.

(c) Pharmaceuticals. A legitimately manufactured pharmaceutical item is not subject to summary forfeiture to the state under subsection (b) of this section, unless it:

(1) has been voluntarily surrendered by an apparently legitimate possessor to a laboratory, law enforcement agency, or peace officer for the express purpose of destruction; or

(2) was illegally sold or possessed under the Texas Health and Safety Code, Chapters 481 - 485.

(d) Doubtful case. If there is doubt about legitimacy or lawfulness, the laboratory, law enforcement agency, or peace officer contemplating destruction must seek a court order of destruction.

(e) Not required to accept an item. This subchapter only applies to an item that has been accepted by a laboratory, law enforcement agency, or peace officer for summary forfeiture or destruction. It does not require a laboratory, agency, or officer to accept a particular item for summary forfeiture or destruction.

§13.153. Item Legally Worthless as Criminal Evidence. (a) Generally. This subchapter describes the documentation and security provisions to use once the decision to destroy has been made.

(b) Reasonable effort. Before a laboratory, law enforcement agency, or peace officer destroys an item under this subchapter, the director recommends but does not require a responsible party to make a reasonable effort to ensure the item:

(1) has no continuing evidentiary value or significance to any pending or contemplated criminal case; or

(2) is in excess quantity.

(c) If case filed. If a criminal case was filed involving an item, the person seeking destruction authorization or contemplating the giving of authorization to destroy must contact the office of the appropriate prosecutor or court before destruction to determine whether the item has any continuing evidentiary significance.

§13.154. Destruction Authority – Controlled Substance Property or Plant. (a) Generally. Destruction with or without court order. A laboratory, law enforcement agency, or peace officer may destroy controlled substance property or a controlled substance plant covered by this section:

(1) with a court order under the authority of that order; or

(2) without a court order under the authority of one of the summary destruction provisions of the Act, Subchapter E.

(b) Statutory sources. A laboratory, law enforcement agency, or peace officer may destroy without a court order:

(1) a controlled substance plant under the authority of the Act, §481.152(d);

(2) an item of controlled substance property under the authority of the Act, §481.153(b); or

(3) an excess quantity of certain items under the authority of the Act, §481.160.

(c) Subchapter applies. The documentation and security provisions of this subchapter apply to destruction of an item of controlled substance property or plant under this section, except where provided otherwise in a court order of destruction.

§13.155. Destruction Authority – Other Item. (a) Destruction with or without court order. A laboratory, law enforcement agency, or peace officer may destroy certain miscellaneous items covered by this section:

(1) with a court order under the authority of that order; or

(2) without a court order under the authority of one of the summary destruction provisions of the Texas Health and Safety Code, Chapters 482 - 485.

(b) Statutory sources. A laboratory, law enforcement agency, or peace officer may destroy without a court order:

(1) a simulated controlled substance under the authority of the Texas Health and Safety Code, §482.004; or

(2) an abusable volatile chemical or inhalant paraphernalia under the authority of the Texas Health and Safety Code, §485.037.

(c) Dangerous drug. At the direction of the Texas State Board of Pharmacy, a law enforcement agency or peace officer may destroy without a court order a dangerous drug under the authority of the Texas Health and Safety Code, §483.074.

(d) Subchapter applies. The documentation and security provisions of this subchapter apply to destruction of a miscellaneous item under this section, except where provided otherwise in a court order of destruction.

§13.156. Destruction Authority – Court Order. (a) Statutory authority. A court may issue an order of destruction for an item that:

(1) is controlled substance property or plant under the authority of the Act, §481.159; or

(2) was stolen or acquired in any other manner that made the acquisition a penal offense under the authority of the Texas Code of Criminal Procedure, Chapter 47.

(b) Security provisions required by the court. A laboratory, law enforcement agency, or peace officer carrying out a court order of destruction must comply with the documentation and security provisions of the order, if any.

(c) No security provisions required by the court. If the court order is silent about the manner of destruction, or if it does not specify or direct another manner of destruction inconsistent with this subchapter, the laboratory, law enforcement agency, or peace officer must comply with the documentation and security provisions of this subchapter.

§13.157. SOP for Destruction by Laboratory or Agency – Security Control. (a) SOP required. Before allowing anyone, whether peace officer or civilian, to destroy an item under this subchapter, a laboratory or law enforcement agency must adopt a written SOP for the destruction of the kind of item sought to be destroyed.

(b) Compliance required. A laboratory or law enforcement agency must require that each person engaged in destruction under this subchapter must strictly follow each SOP. A written SOP may exceed a minimum requirement contained within this subchapter.

(c) Generally. In order to minimize the likelihood of pilferage or other unlawful diversion, an SOP must include requirements that are reasonably likely to:

(1) uncover the occurrence of a discrepancy, loss, theft, or other potential diversion; and

(2) identify and destroy the excess quantity of an item, in order to reduce the size of an exhibit while preserving its evidentiary value.

(d) Modify definition of "excess quantity." With the express approval of each appropriate prosecuting authority, an SOP may increase or decrease the amount of an item necessary to meet the definition of an "excess quantity" under that SOP.

(e) Specifically. An SOP must include a requirement that:

(1) a specific person or category of persons must seek destruction authorization for an item after it exceeds the maximum limits for item storage established by the SOP, including the duration and amount;

(2) a specific person or category of persons must make an immediate report to a supervisor of an unusual or suspicious incident or probable breach of security reasonably related to potential discrepancy, loss, theft, or other diversion;

(3) a supervisor must make a thorough investigation of the incident, including laboratory reanalysis if necessary; and

(4) a specific person or category of persons must contact the submitting peace officer, the submitting law enforcement agency, or the office of the prosecutor responsible for the case to seek:

(A) written authorization to destroy all or part of a particular exhibit; or

(B) blanket written authorization to destroy all or part of each exhibit that meets certain criteria.

§13.158. Manner of Destruction – Security Control. (a) Destruction by anyone. A person may accomplish routine destruction of an item under this subchapter by burning in a suitable incinerator or by another method as long as the person performs the destruction in:

(1) a safe and responsible manner;

(2) compliance with all relevant federal, state, and local laws; and

(3) compliance with all requirements of the Texas Commission on Environmental Quality and the EPA.

(b) Private contract. If a laboratory, law enforcement agency, or peace officer contracts with a private entity to destroy the item, the private contractor must:

(1) hold a controlled substances registration number from the director and DEA; and

(2) obtain full permitting from the EPA as a hazardous waste transportation, storage, or disposal facility, as appropriate.

(c) Destruction by officer. The director recommends but does not require that an individual peace officer should not destroy hazardous material, unless that officer possesses the special expertise required to handle the material safely and lawfully.

§13.159. Two-Witness Rule – Security Control. (a) Destruction by anyone. A laboratory, law enforcement agency, or peace officer may not destroy an item under this subchapter without at least two individuals present to witness the actual destruction. One witness must be:

(1) a supervisor; or

(2) another individual expressly designated by a supervisor to witness that specific destruction incident.

(b) Destruction by laboratory. If a laboratory destroys the item, destruction must comply with:

(1) the security provisions of this chapter for a controlled substances registrant; and

(2) the documentation and security provisions of this subchapter that reference a laboratory.

(c) Destruction by agency or officer. If a law enforcement agency or peace officer destroys the item:

(1) no two individuals may serve as the sole witnesses to consecutive destruction incidents; and

(2) the director recommends but does not require both of the two witnesses should be peace officers from different law enforcement agencies.

§13.160. Destruction Inventory – Security Control. (a) After laboratory analysis. If destruction under this subchapter follows a laboratory analysis process that has resulted in adequate repackaging and sealing of an item, the director will deem a destruction inventory to be sufficient if it consists of an inspection, accomplished without breaking the seal, in order to:

(1) verify the nature, kind, and quantity of the items sought to be destroyed as compared with the original laboratory submission; and

(2) determine the status of the packaging and seal integrity.

(b) No laboratory analysis. If destruction does not follow a laboratory analysis process that has resulted in adequate repackaging and sealing of an item, a destruction inventory must include:

(1) the relevant case or file number;

(2) the name of the seizing law enforcement agency or peace officer;

(3) a description of the packaging;

(4) a description of the status of the packaging and seal integrity; and

(5) the count and weight of the item, including the exact nature, kind, and quantity.

§13.161. Witness Responsibility – Security Control. (a) Generally. For purposes of accountability, at least two of the witnesses to a destruction under this subchapter must, during a process conducted immediately before the physical destruction of an item:

(1) examine each item in a manner sufficient to complete the destruction inventory required by this subchapter;

(2) compare that destruction inventory with each previous inventory of the item, including one that may have been made as part of an evidence submission form, a laboratory analysis, or as part of the destruction authorization;

(3) examine each package for the integrity or breach of the package or seal;

(4) refuse to destroy an item that reasonably appears to have been tampered with or to be at variance with its purported count or weight; and

(5) ensure destruction of each item as soon as reasonably possible.

(b) Suspicious incident. Each witness must:

(1) investigate a suspicious incident or probable breach of security, including a discrepancy, loss, theft, or other potential diversion of an item to be destroyed; or

(2) report the incident or breach to an appropriate law enforcement agency or peace officer for investigation.

(c) Registrant security provisions may also apply. The registrant security provisions of this chapter apply if a witness to destruction under this subchapter is also registered individually as a controlled substances registrant or employed by a registrant. If so, the witness is responsible for making a written report to the director through the Narcotics Regulation Bureau of a probable breach of security under those provisions.

§13.162. Laboratory Retesting for Possible Tampering – Security Control. (a) Suspicious incident. Unless there is an obvious, reasonable explanation for the event in question, each witness to a destruction under this subchapter is responsible for returning an item to a laboratory for testing to detect a discrepancy, loss, theft, or other potential diversion if:

(1) the count or weight of the item is substantially incorrect;

(2) a package has been opened; or

(3) there is another suspicious incident or probable breach of security.

(b) Laboratory options. If an individual returns an item to a laboratory for testing under this section, the laboratory may conduct an analysis sufficient to detect discrepancy, loss, theft, or other potential diversion or to resolve the particular suspicion surrounding the incident.

§13.163. Destruction Documentation – Security Control. (a) Contemporaneous written statement. At or immediately after the time of a destruction under this subchapter, one of the witnesses to destruction must complete a written statement containing a detailed description of the destruction of the item, including all the relevant information required by this subchapter.

(b) Private contract. If a laboratory, law enforcement agency, or peace officer contracts with a private entity to destroy the item, the witnesses need not be present during the actual physical destruction of each item by the private contractor. A written statement under this subsection must document the status and handling of the item up to the point the laboratory, agency, or officer turned it over to the private contractor for destruction under the contract.

(c) Contents of statement. A statement may incorporate other documents by reference and must contain:

(1) relevant seizure information, including the seizing law enforcement agency or peace officer, the date and location of seizure, and the authority for seizure;

(2) the destruction authority, including the name, position, and reason given by the individual authorizing destruction;

(3) the manner of transportation to the destruction site, including the names of each individual transporting an item;

(4) an inventory of the items destroyed, including the nature, kind, and quantity of the item;

(5) the witnesses, including the name, title, agency, and signature of each witness;

(6) the date and location of destruction;

(7) manner of destruction; and

(8) each unusual or suspicious event that occurred during the destruction incident.

§13.164. Document Maintenance, Inspection, and Transmittal – Security Control. (a) Generally. The laboratory, law enforcement agency, or peace officer who destroys an item under

this subchapter must maintain the original destruction documents in a readily retrievable form after the date of destruction.

(b) Available to Director for inspection. The destroying laboratory, law enforcement agency, or peace officer must make the original destruction documents available for announced or unannounced inspection by the director.

(c) Copy upon request. If the director requests a copy of the destruction documentation, a laboratory, law enforcement agency, or peace officer destroying an item subject to this subchapter must provide the copy to the director within seven days.

(d) Destruction standard operating procedure (SOP). A laboratory or law enforcement agency adopting a written destruction SOP under this subchapter must:

(1) maintain the original copy of the SOP;

(2) make the original available for announced or unannounced inspection by the director or a member of the department; and

(3) provide the copy to the director under this section in the same manner as another destruction document.

§13.165. Communication with Director (Crime Lab Service). If a person is required or allowed by this subchapter to make a notification, report, or other written, telephonic, or personal communication to the director, the person must make the communication to the director through the Crime Laboratory Service at the address indicated in §13.11 of this title (relating to Telephone Number and Address - Crime Laboratory Service).

Subchapter H. Security

§13.181. Subchapter Definitions. The following words and terms, when used in this subchapter, have the following meanings, unless the context clearly indicates otherwise: Distributor--Includes a precursor or apparatus distributor under Subchapter E of this chapter (relating to Precursors and Apparatus).

§13.182. Registrant – Generally. (a) To prevent diversion. A registrant and an applicant for registration must establish and maintain effective controls and procedures required directly or indirectly by this subchapter in order to prevent unauthorized access, theft, or diversion of a controlled substance from the legitimate to the illicit market.

(b) Lawful use. A registrant may only use a controlled substance for a lawful purpose, including:

(1) in a field of medicine, veterinary medicine, dentistry, pharmacy, or other health care profession;

(2) scientific research;

(3) delivery or sale to an authorized person; or

(4) in industrial channels.

(c) Other rules apply. Except as otherwise provided by this subchapter, a registrant must comply with the physical and other related security control provisions of the Code of Federal Regulations, Title 21, Chapter II, §§1301.71 - 1301.76. Additionally, the emergency medical storage lockers must be so attached to the vehicle, aircraft or vessel as to prevent removal for theft or diversion of the controlled substances. The director does not impose any security

requirements on a peyote distributor under Subchapter C of this chapter (relating to Peyote) in addition to these federal requirements.

(d) Access control. During the regular course of business activities, a facility registered under the Act may not allow access by an individual to the facility's controlled substance storage area unless the individual is someone whose presence is authorized and required for efficient operation of the facility.

(e) Cabinet security. Except as provided by subsections (c) or (f) of this section, a registrant must store a controlled substance in a securely locked, substantially constructed cabinet or other security cabinet that meets federal security requirements.

(f) Constructive compliance. Although a cabinet fails to meet the security requirements of this section, the director may deem the cabinet to be in compliance if it is located in a room or area:

(1) to which the entrance door has been constructed so the hinge mountings inhibit removal; and

(2) for which a limited number of employees have keys or combinations to operate its locking device.

(g) Lock security. A registrant must:

(1) rekey a key lock if a key is lost or upon termination of an employee having possession of a key; and

(2) change a combination lock number:

(A) if a record of the combination is lost or stolen; or

(B) upon termination of an employee having knowledge of the combination.

§13.183. Pharmacy Registrant. A facility registered as a pharmacy must comply with each rule of the Texas State Board of Pharmacy related to access, responsibility, and other security issues.

§13.184. Registrant’s Employee. (a) Disqualification. A registrant may not intentionally, knowingly, or recklessly employ or use in any manner an individual who will or is reasonably likely to have access to a controlled substance and who:

(1) has had a federal or state application for controlled substances registration denied, revoked, canceled, or suspended;

(2) has been convicted of a felony offense under a state or federal law;

(3) does not comply with a federal security control for a practitioner under the Code of Federal Regulations, Title 21, Chapter II, §1301.76;

(4) does not meet a federal employee screening standard for a non-practitioner under the Code of Federal Regulations, Title 21, Chapter II, §§1301.90 - 1301.93; or

(5) has had a license revoked, canceled, or suspended by a state health regulatory agency.

(b) Disqualification waived. After considering the registrant's written request, the director may allow the registrant to employ an individual who has violated subsection (a) of this section. The director may not waive the requirements that a registrant not hire an individual during the two-year period immediately following the individual's conviction for a felony offense under state or federal law or until the terms of a sentence are satisfied, whichever is the longer period of time.

(c) Factors. Before making a waiver decision, the director may consider each relevant factor, including, but not limited to, the following:

(1) if the individual is a convicted felon, the suspension of sentence, placement of the individual on probation, and the successful completion by the individual of a court-ordered supervision;

(2) whether the health regulatory agency has reinstated or reissued the previously revoked, canceled, or suspended license of the individual; and

(3) whether the employment of that individual by a registrant is in the best interest of the public and the individual.

§13.185. Official Prescription Form. (a) Accountability. A practitioner who obtains from the director an official prescription form is accountable for each numbered form.

(b) Prohibited acts. A practitioner may not:

(1) allow another practitioner to use the individual practitioner's official prescription form;

(2) pre-sign an official prescription blank;

(3) post-date an official prescription; or

(4) leave an official prescription blank in a location where the practitioner should reasonably believe another could steal or misuse a prescription.

(c) While not in use. While an official prescription blank is not in immediate use, a practitioner may not maintain or store the book at a location so the book is easily accessible for theft or other misuse.

(d) Voided. A practitioner must account for each voided official prescription form by sending the voided form to the director (Texas Prescription Program).

(e) Types of forms. Forms may be single or multiple copy forms as provided by the department.

(f) Faxed forms. Faxed official prescription forms will be accounted for as in the Act, §481.074(o).

§13.186. Precursor or Laboratory Apparatus. (a) Required unless one-time permit. A distributor or recipient of a precursor or apparatus must comply with this subsection:

(1) unless the person is exempted or excepted from similar security requirements by this chapter or the Act, §481.077(k) or §481.080(l) as a one-time permit holder; or

(2) even though the person is exempted or excepted as described in paragraph (1) of this subsection, the person has voluntarily submitted to annual permitting under this chapter.

(b) Storage requirements. A business, distributor, or individual who holds a precursor chemical or laboratory apparatus permit will meet the following minimum security requirements to protect these controlled items. The permit holder will:

(1) establish and maintain a building, an enclosure within a building, or an enclosed yard that provides reasonably adequate security against the diversion of a controlled item;

(2) limit access to each storage area to the minimum number of individuals or employees necessary for the permit holder's activities; and

(3) designate an individual or a reasonably limited set of individuals with:

(A) responsibility for each area where a controlled item is stored; and

(B) authority to enter or control entry into the area.

(c) No physical barrier. In the absence of a physical barrier, such as a wall, partition, fence, or similar divider, the permit holder may comply with this section by another form of substantially increased security to limit physical access to the storage area under subsection (b)(2) of this section.

(d) Written designation. The permit holder will make the designation required by subsection (b)(3) of this section in writing and will make the designation available upon request in the same manner as a record kept under this chapter. The holder may update the designation record as necessary to reflect current practice.

(e) Observation. When maintenance personnel or a business guest, visitor, or similar individual is present in or passes through, an area covered by this section, the permit holder must provide for reasonably adequate observation of the area by an employee specifically designated under subsection (b)(3) of this section.

(f) Alarm system. If a permit holder has an alarm system that is in operation and being monitored, the permit holder must immediately report each unauthorized intrusion or other security breach to:

(1) a local law enforcement agency; or

(2) the director (PCLAS).

(g) No risk of diversion. A permit holder is not required to make the alarm report required under subsection (f) of this section, if there is a clearly innocent or other reasonable explanation for the security breach that does not involve a potential of diversion.

(h) Limited risk of diversion. The director may waive a security requirement of this section if a permit holder or applicant demonstrates that business procedures or other circumstances impose a more strict security requirement that indicates a significantly limited risk of diversion.

§13.187. Minimum Standards. A standard contained in this subchapter is a minimum standard and may be exceeded where desirable or appropriate.

Subchapter I. Record Keeping

§13.201. Subchapter Definitions. The following words and terms, when used in this subchapter, have the following meanings, unless the context clearly indicates otherwise.

(1) **Distributor** – Includes a peyote distributor under Subchapter C of this chapter (relating to Peyote) and a precursor or apparatus distributor under Subchapter E of this chapter (relating to Precursors and Apparatus).

(2) **Lawful possession** – Includes possession of a precursor or apparatus obtained in accordance with state or federal law.

§13.202. Receipt or Disposition of Controlled Substance. (a) Records required. A registrant must:

(1) maintain each record required to be kept under the Act or this chapter; and

(2) make the record available for inspection and copying by an individual described by §13.233 of this title (relating to Who May Inspect).

(b) When made. A registrant must:

(1) make the record contemporaneously with the event recorded; and

(2) ensure the record is kept current.

(c) Content. A registrant must keep a complete and accurate record of each:

(1) purchase or other acquisition of a controlled substance, including samples;

(2) disposal of a controlled substance; and

(3) dispensing of a Schedule V controlled substance by a pharmacist or intern to a retail purchaser without a prescription, in full compliance with federal law and regulations, state law, and the rules of the Texas State Board of Pharmacy.

(d) Other rules apply. A record of a purchase, acquisition, disposal, or dispensing of a controlled substance must include the information required under:

(1) the Code of Federal Regulations, Title 21, Chapter II, Part 1304; and

(2) the rules of each appropriate state health regulatory agency governing the conduct of the registrant.

(e) Accountability. A registrant must comply with the accountability provisions for disposal of an unused quantity of a controlled substance required under:

(1) the Code of Federal Regulations, Title 21, Chapter II, §1307.21; and

(2) the rules of each appropriate state health regulatory agency governing the conduct of the registrant.

(f) No printer. If a person maintains a record under this chapter using an automated data processing system and if the person does not have a printer available on site, then the individual:

(1) must make a useable copy available to an individual listed in subsection (a) of this section at the close of business the day after the audit; and

(2) who provides the copy, must certify that the information contained within the copy:

(A) is true and correct as of the date of audit; and

(B) has not been altered, amended, or modified.

§13.203. Order Forms (DEA Form 222). A registrant must comply with the order form provisions for a controlled substance required under:

(1) the Code of Federal Regulations, Title 21, Chapter II, Part 1305; and

(2) the rules of each appropriate state health regulatory agency governing the conduct of the registrant.

§13.204. Pharmacy Registrant. A registrant who possesses, completes, fills, or processes a prescription must comply with the record keeping provisions for a prescription, including labeling, required under:

(1) the Code of Federal Regulations, Title 21, Chapter II, Part 1306; and

(2) the rules of each appropriate state health regulatory agency governing the conduct of the registrant.

§13.205. Practitioner's Designated Agent. (a) Prohibitions. A practitioner may designate another individual as an agent of the practitioner unless the designation is a subterfuge intended to circumvent materially the effect of a denial, suspension, revocation, or similar disciplinary action taken by the director, DEA, or a related health regulatory agency.

(b) Other rules apply. A practitioner who designates another individual as an agent must comply with each relevant provision of a federal regulation or rule of a state health regulatory agency governing the conduct of the practitioner.

(c) Requirements to be designated. A designated agent must be:

(1) a registered nurse licensed in this state;

(2) a licensed vocational nurse licensed in this state;

(3) a physician assistant licensed in this state; or

(4) an employee who is:

(A) located in the practitioner's office; and

(B) a member of the health care staff of the office.

(d) Current list. A practitioner must maintain in the practitioner's usual place of business a current written list of each individual designated as an agent under this section.

(e) List provided. When a practitioner adds an individual to or deletes an individual from the list, the practitioner must provide upon request the current list to a pharmacy or pharmacist, the director, a member of the department, or an investigator listed in the Act, §481.076(a)(1).

§13.206. Precursor/Apparatus Records. (a) Required unless one-time permit. A distributor or recipient of a precursor or apparatus must maintain records under this section:

(1) unless the person is exempted or excepted from reporting by this chapter or the Act, §481.077(k) or §481.080(l) as a one-time permit holder; or

(2) even though the person is exempted or excepted as described in paragraph (1) of this subsection, the person has voluntarily submitted to annual permitting under this chapter.

(b) Distributor. A distributor of a precursor or apparatus must:

(1) make an accurate and legible record of a distribution; and

(2) maintain the record after the date of the transaction.

(c) NAR-22. Copy 2 of a properly completed DPS Form NAR-22 meets the record keeping requirement of this section while it remains in the distributor's record booklet.

(d) Readily retrievable. The distributor satisfies the record keeping requirement under this section by recording and maintaining the record of distribution as a readily retrievable record in an automated data processing system, if the system provides a comprehensive monthly report to the director (PCLAS).

(e) Letter of authorization. A distributor must keep an original letter of authorization on file after the date of transaction. A distributor may, but need not demand to, see, copy, or keep a letter of authorization from a recipient if the recipient has an annual permit.

(f) Exception. This section does not apply to a recipient who:

(1) has lawful possession of a precursor or apparatus; and

(2) is excepted from the permit requirements of Subchapter E of this chapter (relating to Precursors and Apparatus).

(g) Limited risk of diversion. The director may waive a record keeping requirement of this section if a permit holder or applicant demonstrates that business procedures or other circumstances impose a more strict record keeping requirement that indicates a significantly limited risk of diversion.

§13.207. Record Retention Period. (a) Two years, generally. Except as otherwise provided by law or this chapter, a record required to be made or kept by the Act or this chapter must be kept, maintained, and made available for inspection or copying for a period of two years.

(b) Beginning date. The two-year period described by this section commences on the later date of the day:

(1) the record was required to be created;

(2) the record was actually created; or

(3) the prescription was last filled.

§13.208. Requirement to Update Information. A person, who is an applicant for or holder of a registration, a temporary registration or annual permit from the director, must notify the director through the appropriate section of the Narcotics Regulation Bureau before the seventh day after any change in the person's business name, address, physician delegating prescriptive authority, and telephone number or other information required on the application, registration, or permit.

§13.209. Minimum Standards. A standard contained in this subchapter is a minimum standard and may be exceeded where desirable or appropriate.

Subchapter J. Inventory

§13.221. Subchapter Definitions. The following words and terms, when used in this subchapter, have the following meanings, unless the context clearly indicates otherwise: Distributor--Includes a peyote distributor under Subchapter C of this chapter (relating to Peyote) and a precursor or apparatus distributor under Subchapter E of this chapter (relating to Precursors and Apparatus).

§13.222. Controlled Substance Inventory. A registrant must establish and maintain an inventory for a controlled substance as required under:

(1) the Code of Federal Regulations, Title 21, Chapter II, Part 1304; and

(2) the rules of each appropriate state health regulatory agency governing the conduct of the registrant.

§13.223. Precursor/Apparatus Inventory. (a) Required unless one-time permit. A distributor or recipient of a precursor or apparatus must establish and maintain an inventory under this section:

(1) unless the person is exempted or excepted from inventory requirements by this chapter or the Act, §481.077(k) or §481.080(l) as a one-time permit holder; or

(2) even though the person is exempted or excepted as described in paragraph (1) of this subsection, the person has voluntarily submitted to annual permitting under this chapter.

(b) Initial inventory. A distributor or recipient must conduct an initial inventory to include each precursor or apparatus that is covered by this subchapter and in stock at the time of the inventory. The distributor or recipient must conduct the initial inventory not later than the 90th day after the date the director issues the initial permit under this chapter.

(c) Additional inventory. After the initial inventory, a distributor or recipient must conduct another inventory not later than the 24th month following the month of the last inventory.

(d) Constructive compliance. The director will deem a distributor or recipient to be in compliance with the inventory requirements of this section if the distributor or recipient:

(1) is a business that routinely conducts an annual inventory of all items; and

(2) maintains a readily retrievable record of each precursor or apparatus located during the inventory.

(e) Limited risk of diversion. The director may waive an inventory requirement of this section if a permit holder or applicant demonstrates that business procedures or other

circumstances impose a more strict inventory requirement that indicates a significantly limited risk of diversion.

(f) One-time permit holder. This subchapter does not apply to the holder of a one-time permit for distribution or receipt of a precursor or apparatus under §13.104 of this title (relating to Requirements for Permit Issuance).

§13.224. Minimum Standards. A standard contained in this subchapter is a minimum standard and may be exceeded where desirable or appropriate.

Subchapter K. Inspection

§13.231. Subchapter Definitions. The following words and terms, when used in this subchapter, have the following meanings, unless the context clearly indicates otherwise: Distributor--Includes a peyote distributor under Subchapter C of this chapter (relating to Peyote) and a precursor or apparatus distributor under Subchapter E of this chapter (relating to Precursors and Apparatus).

§13.232. Location Subject to Inspection. (a) An individual named in §13.233 of this title (relating to Who May Inspect) may inspect the controlled premises of an applicant for or holder of:

(1) a controlled substances registration under Subchapter B of this chapter (relating to Registration);

(2) a peyote distributor registration under Subchapter C of this chapter (relating to Peyote); or

(3) a precursor or apparatus permit under Subchapter E of this chapter (relating to Precursors and Apparatus).

(b) The controlled premises of an applicant for or holder of a registration or permit includes each location where an item or record covered by this chapter is stored, used, or transferred within the holder's business or activity.

§13.233. Who May Inspect. (a) Generally. This subchapter applies to the director's authority under the Act to enter and inspect controlled premises. While engaged in the inspection or an activity reasonably related to the inspection, the director may examine, audit, inventory, or, as appropriate, copy an item or record found on the premises.

(b) Delegation. The director delegates authority described in subsection (a) of this section to each member of the department who is assigned to the Criminal Investigations Division or the Narcotics Regulation Bureau, whether or not the member is a commissioned peace officer.

(c) Assistance. When exercising an authority described in subsections (a) or (b) of this section, the director or member may be assisted by:

(1) a peace officer;

(2) another member of the department;

(3) a member of DEA;

(4) an investigator listed in the Act, §481.076(a)(1);

(5) a representative of an appropriate state health regulatory agency governing the conduct of a registrant; or

(6) another individual acting under the authority of the director or member.

§13.234. Time Limitations. (a) For the purpose of examining, auditing, inspecting, inventorying, or, where appropriate, copying an item subject to the Act or a record required to be made or kept under the Act or this chapter, the director or a member of the department may enter the controlled premises of an applicant or registrant at a reasonable time, including:

(1) normal business hours; or

(2) at another time when the controlled premises are occupied or open to the public.

(b) Upon request of the director, a registrant or permit holder has 24 hours, excluding weekends and holidays, to produce any or all records required to be maintained on site for inspection by the department.

(c) All registrants that are authorized to maintain an off site central record keeping system, for all records permitted to be maintained off site, shall comply with the Code of Federal Regulations, Title 21, Chapter II, Section 1304.04(b), which provides for a two business day time period to produce the records upon written request.

§13.235. Interference With Inspection. (a) Prohibited. If the Act or this subchapter authorizes an inspection, no individual in charge of a premise, item, or record covered by this subchapter may refuse or interfere with any of the following activities related to the inspection:

(1) entry to the premises;

(2) examination, audit, inspection, or inventory of the item or record;

(3) copying a record or related document; or

(4) sampling each chemical, drug, substance, precursor, or similar substance on the premises.

(b) One-time permit. Refusal or interference by an applicant for a one-time permit may be a ground for the director to deny the permit application.

§13.236. What May Be Inspected. (a) Generally. Except as provided in subsections (b) or (c) of this section, the director may examine, audit, inspect, inventory and, where appropriate, copy:

(1) a record, report, or other document required to be made or kept under the Act;

(2) the security of the controlled premises; and

(3) each of the following records or controlled items if found on the premises:

(A) pertinent equipment;

(B) a chemical precursor or laboratory apparatus;

(C) a finished or unfinished drug;

(D) another substance, material, container, or labeling subject to the Act;

(E) all files, papers, processes, controls, or facilities appropriate for verification of a record required to be made or kept under the Act or otherwise bearing on the provisions of the Act;

(F) a stock of a controlled substance;

(G) a hypodermic syringe, needle, pipe, or other instrument, device, contrivance, equipment, control, container, label, or facility relating to a possible violation of the Act; or

(H) material used, intended to be used, or capable of being used as an adulterant or dilutant.

(b) Dispensing only. If an applicant has only sought or obtained a controlled substances registration to dispense the substance, the director may only inspect the records of the applicant or registrant. Under this subsection, the director may not examine, audit, inspect, inventory, or copy another item described in subsection (a) of this section.

(c) Prohibitions. Unless the owner, operator, or agent in charge of a controlled premises consents in writing, the director may not examine, audit, inspect, inventory, or copy:

(1) financial data;

(2) sales data (other than shipment data); or

(3) pricing data.

§13.237. Inspection of Permit Holder and Pseudoephedrine Records and Reports. (a) Generally. The holder of a permit for distribution or receipt of a chemical precursor or laboratory apparatus may be inspected subject to the limitations of the Act, §481.077(k), §481.080(l) and §13.104 of this title (relating to Requirements for Permit Issuance).

(b) Consent to inspect - one-time. An applicant for a one-time permit must give written consent for one or more pre-permit inspections under this subchapter to determine eligibility for issuance of the permit. A written consent to an inspection under the Act, §481.078(e) or §481.081(e), is sufficient for a one-time permit if the consent is for initial inspection or any additional inspection to be conducted before issuance of the permit and at a reasonable time as necessary to determine qualification for the permit.

(c) Consent to inspect - annual. A written consent given by a person seeking an annual permit must include consent for an initial inspection to determine qualification for the permit sought and additional inspections conducted before or after issuance of the permit at a reasonable time as necessary to enforce the Act or this chapter.

(d) Pseudoephedrine Records and Reports.

(1) Generally. A wholesale distributor who distributes a product containing ephedrine, pseudoephedrine, or norpseudoephedrine to a retailer shall make available for immediate inspection to any member of the department during regular business hours upon presentation of proper credentials all files, papers, processes, controls, or facilities appropriate for verification of a required record or report. If the wholesaler is no longer in operation or closed, the records shall be made available within three (3) business days.

(2) Delegation. The director delegates authority described in this section to each member of the department who is assigned to the Narcotics Regulation Bureau, whether or not the member is a commissioned peace officer.

(3) Assistance. When exercising the authority in this section, a member of the department may be assisted by:

(A) a peace officer;

(B) another member of the department;

(C) a member of DEA;

(D) a representative of an appropriate state health regulatory agency governing the conduct of a wholesaler; or

(E) another individual acting under the authority of the director or member.

(e) Statutory authority. A member of the department or peace officer is expressly authorized by the Act, §481.077(k) and §481.080(l), to audit, inspect, and copy a record of a purchase or sale of a precursor or apparatus of a person who holds an annual permit under

Subchapter E of this chapter (relating to Precursors and Apparatus). Except as provided by subsection (b) of this section, this section does not apply to a person who holds a one-time permit.

Subchapter L. Reporting Discrepancy, Loss, Theft, or Diversion

§13.251. Subchapter Definitions. The following words and terms, when used in this subchapter, have the following meanings, unless the context clearly indicates otherwise.

(1) **Distributor** – Includes a peyote distributor under Subchapter C of this chapter (relating to Peyote) and a precursor or apparatus distributor under Subchapter E of this chapter (relating to Precursors and Apparatus).

(2) **Item** – Includes:

(A) a controlled substance, including peyote;

(B) a precursor chemical;

(C) laboratory apparatus; or

(D) an official prescription form.

§13.252. Applicability. (a) Discrepancy, loss, theft, or other potential diversion. Without regard to actual evidence of diversion, this subchapter applies to a discrepancy, loss, or theft of a controlled or other regulated item or substance or other situation involving a potential for diversion.

(b) Who must report. This subchapter applies to a person who is:

(1) a registrant under Subchapter B of this chapter (relating to Registration);

(2) a registered peyote distributor under Subchapter C of this chapter (relating to Peyote); or

(3) a precursor or apparatus permit holder under Subchapter E of this chapter (relating to Precursors and Apparatus), whether it is a one-time or annual permit.

§13.253. Reporting Discrepancy, Loss, Theft, or Other Potential Diversion. (a) Generally. A person covered by this subchapter must notify the director not later than the third day after the date the person learns of:

(1) a discrepancy in the amount of an item ordered from a source inside or outside this state and the amount received, if not back ordered;

(2) a loss or theft during shipment from a source inside or outside this state; or

(3) a loss or theft from current inventory.

(b) How made. A person covered by this subchapter must notify the director by submitting a report to the director through the appropriate section of the Narcotics Regulation Bureau. The report must be made on:

(1) a DPS Form NAR-91, for a registrant under Subchapter B of this chapter (relating to Registration) or Subchapter C of this chapter (relating to Peyote);

(2) a DPS Form NAR-91B, for a precursor or apparatus permit holder under Subchapter E of this chapter (relating to Precursors and Apparatus); or

(3) a duplicate of the equivalent DEA form for reporting a theft or loss of a controlled substance to DEA.

(c) Form and content. A person making a report under this section must:

(1) make the report on regular business letterhead or other reporting form; and

(2) ensure the report contains the following information:

(A) the name, address, and telephone number of the business or other person preparing the report;

(B) the printed or typed name of the individual preparing the report; and

(C) the date the person prepares the report.

(d) Additional content. If the report under this section is of:

(1) a discrepancy, it must include:

(A) the name of the item ordered;

(B) the difference in the amount actually received; and

(C) the amount shipped according to the shipping statement or invoice.

(2) a loss or theft from current inventory, it must include:

(A) the name and amount of the item lost or stolen;

(B) the physical location where the loss or theft occurred; and

(C) the date of discovery of the loss or theft.

(3) a discrepancy, loss, theft, or other potential diversion that occurred during shipment of the item, it must include:

(A) the name of the common carrier or person who transported the item; and

(B) the date the item was shipped.

§13.254. Official Prescription. (a) Report lost forms. Not later than close of business on the day of discovery, a practitioner must report a lost or stolen official prescription form to:

(1) the local police department or sheriff's office in an effective manner; and

(2) the director (Texas Prescription Program) by telephone at the number indicated in §13.9 of this title (relating to Telephone Number and Address - Texas Prescription Program).

(b) Recovery report. Not later than close of business on the day of recovery of an official prescription form previously reported lost or stolen, a practitioner must, before using the recovered form, notify:

(1) the local law enforcement agency to which the matter was originally reported; and

(2) the director (Texas Prescription Program).

(c) Replacement/lost form. Note later than the close of business on the day that an official prescription is replaced or reported lost, with or without a replacement, the prescribing practitioner, or designated agent, shall report to the director (Texas Prescription Program) the following:

(1) patient name, address, date of birth or age;

(2) all drug information; and

(3) official prescription for DPS control number.

Subchapter M. Denial, Revocation, and Related Disciplinary Action

§13.271. Subchapter Definitions. The following words and terms, when used in this subchapter, have the following meanings, unless the context clearly indicates otherwise.

(1) **APA** – The Administrative Procedure Act (Texas Government Code, Chapter 2001).

(2) **Applicant** – Person who applies for a registration or permit.

(3) **Denial** – Includes an action to deny an application for an original or renewal of a registration or permit.

(4) **Disciplinary action** – An action taken under this subchapter to accept a voluntary surrender or to reprimand, cancel, suspend, probate, revoke, or demonstrate expiration or termination of a current or former registration.

(5) **Registrant** – A person who holds a current or former registration or permit.

(6) **Registration** – A controlled substances registration, including a peyote distributor registration or a precursor or apparatus permit issued under this chapter.

(7) **Serious misdemeanor** – A Class A misdemeanor, a Class B misdemeanor, or another criminal offense punishable under the laws of this state, another state, or the United States by:

(A) confinement in a county jail or analogous penal institution; or

(B) a term of confinement of one year or less, if the jurisdiction does not differentiate between the location of felony or misdemeanor confinement.

§13.272. General Provisions. (a) APA applies. Except as provided by this chapter, the APA applies if the director proposes to take disciplinary action against a person's registration or to deny a person's application for registration.

(1) The person is entitled to preliminary notice from the director and a hearing as a contested case under the APA.

(2) The director will send notice by certified mail or personal delivery to the most current address of the registrant or applicant contained in the director's files. If mailed, the notice is presumed to have been received by the registrant or applicant on the third business day after the date of mailing.

(b) Pleadings. If the director pleads appropriately:

(1) the director may take a disciplinary action or make a denial under this subchapter against a chemical precursor or laboratory apparatus permit in the same manner as a disciplinary action or denial against a controlled substances registration; and

(2) a successful disciplinary action or denial by the director will also operate against any other registration issued by the director under this chapter.

(c) Action may be limited. The director may limit a disciplinary action or denial to the particular activity, schedule, controlled substance within a schedule, precursor, apparatus, or other item for which grounds for the action exist.

(d) Notification of another agency. The director will promptly notify each appropriate federal or state health regulatory agency of an order taking a disciplinary action or denial against a registration or application, other than a permit issued under Subchapter E of this chapter (relating to Precursors and Apparatus).

(e) Invalidation. A registration may:

(1) expire or terminate;

(2) be canceled, surrendered, suspended, revoked, or otherwise invalidated; or

(3) be subject to reprimand or probation.

(f) Possession. Mere possession of the physical document does not necessarily mean that the person:

(1) still holds a current, valid registration; or

(2) currently holds, has ever held, or has any of the powers or rights indicated on the document.

(g) Hearing, evidence and procedure. Except as provided by this chapter, a hearing will be governed by the APA and will be held by an administrative law judge appointed by the State Office of Administrative Hearings. A hearing will be conducted in accordance with the procedures contained in Chapter 29 of this title (relating to Practice and Procedure), and the rules of the State Office of Administrative Hearings.

(h) Under the Act, §481.063(h), the APA does not apply to a denial, suspension, or revocation of an application for registration if the denial is based on a denial or other disciplinary action taken by DEA under the Federal Controlled Substances Act.

(i) Request for Hearing. An applicant or registrant may request a hearing under this subchapter, unless otherwise stated in the Act, by submitting a timely and properly addressed written request for a hearing to the director. To be timely, the request must be received by the director no later than fifteen calendar days after the date of the registrant's or applicant's receipt of the notice of denial or other disciplinary action. To be properly addressed, a request for hearing must be mailed or sent by e-mail or facsimile to the director at the return address included in the director's notice of denial or other disciplinary action or, if none, to the director at the address of the Narcotics Regulation Bureau indicated in §13.7 of this title (relating to Telephone Number and Address - Narcotics Regulation Bureau).

§13.273. Denial. (a) Grounds. Except as provided by §13.274(b) of this title (relating to Revocation), the director may deny an application for registration and may refuse issuance of the appropriate registration if:

(1) the applicant has not affixed a signature required by this chapter;

(2) a required form is incomplete;

(3) a required document is incomplete, illegible, or missing;

(4) the application contains a false assertion by any person;

(5) the applicant has a registration currently revoked, suspended, or voluntarily surrendered;

(6) the applicant would not qualify for a registration under the Act, §481.063(e); or

(7) the applicant does not qualify under this chapter for issuance of registration.

(b) Hearing. An applicant may request a hearing upon denial or refusal under this section, unless otherwise stated in the Act. If the director prevails at the hearing, the director may issue final order of denial.

§13.274. Revocation. (a) Grounds. The director will revoke a registration if the registrant:

(1) violates a ground of denial described in the Act, §481.063(e);

(2) violates a section of this chapter where revocation is the penalty noted; or

(3) has a license or similar permit permanently revoked by an appropriate federal or state health regulatory agency.

(b) Effect on later application. Except as provided by this subsection, a person may not apply for registration until one year after the date a revocation became legally final.

(1) Within that year, the director will not reinstate a revoked registration unless the registrant submits a new application and proof by a preponderance of evidence that the facts supporting the revocation have been negated or otherwise substantially changed, such as:

(A) the felony conviction has been reversed or set aside on direct or collateral appeal, or a pardon based on subsequent proof of innocence has issued; or

(B) the license or similar permit was not permanently revoked by an appropriate federal or state health regulatory agency.

(2) After that year, the director will not reinstate a revoked registration unless the registrant submits a new application and:

(A) proof described by Subsection (b)(1) of this section; or

(B) a showing of good cause for the new registration.

(c) After invalidation. The director may revoke a registration even though it has become invalidated by some other means, such as:

(1) cancellation, expiration, or termination;

(2) suspension;

(3) voluntary surrender; or

(4) any other means.

(d) Hearing. Upon revocation under this section, the registrant may request a hearing, unless otherwise stated in the Act. If the director prevails at the hearing, the director may issue a final order of revocation.

§13.275. Suspension. (a) Grounds. Unless revocation is explicitly noted, the director may suspend a registration if the registrant:

(1) violates a provision of:

(A) these sections; or

(B) the Act; or

(2) has a license or similar permit suspended for a stated term by an appropriate federal or state health regulatory agency.

(b) Term, generally. Unless otherwise specified in subsections (c) and (d) of this section, the term of suspension is 12 months.

(c) Special term. The director may impose the same term as a court or federal or state health regulatory agency imposed in the underlying matter and if the court's judgment or adjudication is deferred for a felony or serious misdemeanor and the registrant is then placed on probation or community supervision, the term of suspension may be equal to the actual time served on probation.

(d) Additional term. Up to twelve months may be added to the term of a new suspension for each separate previous violation that has resulted in either a suspension, a probated suspension, or a written reprimand before the beginning date of the new suspension.

(e) Beginning date. A suspension or probation may be ordered to run concurrently or consecutively with another suspension or probation. The beginning date of the suspension is:

(1) a date agreed to by both parties that is no earlier than the date of the violation on which the action is based; or

(2) the earlier of the date:

(A) the registrant notifies the director in writing of the violation if the director later receives a signed waiver of a suspension hearing from the registrant that was postmarked within 10 days of its receipt by the registrant; or

(B) the suspension became legally final.

(f) End of suspension. A suspended registration remains suspended until one of the following events occurs.

(1) Before expiration of the terms of suspension and registration:

(A) the remainder of the suspension is probated; or

(B) a written request for reinstatement of the original registration is received from the registrant and accepted by the director based on good cause shown.

(2) After expiration of the term of suspension and before expiration of the term of registration, a written request for reinstatement of the original registration is received from the registrant and accepted by the director.

(3) After expiration of the terms of suspension and registration, a written application for a new registration is received from the registrant and accepted by the director.

(g) Suspension after invalidation. The director may suspend a registration even though it may have become invalid by some other means, such as:

(1) cancellation, expiration, or termination;

(2) voluntary surrender; or

(3) any other means.

(h) Hearing. Upon suspension under this section, the registrant may request a hearing, unless otherwise stated in the Act. If the director prevails at the hearing, the director may issue a:

(1) final order of suspension; or

(2) final order of written reprimand under this subchapter.

§13.276. Probation or Reprimand. (a) Probation or reprimand. With the agreement of the parties, the director may, upon proof of mitigating factors:

(1) probate all or part of the suspension term; or

(2) issue a written reprimand in lieu of suspension.

(b) Probation period. If probated, a suspension:

(1) may be probated for a period of up to twice the maximum term of suspension; and

(2) may not be probated for less than six months.

(c) Probation terms. The director may impose reasonable terms or conditions of probation, such as:

(1) special reporting conditions;

(2) special document submission conditions;

(3) no further rule or law violations; or

(4) any other reasonable term of probation.

(d) End of probation. A probated registration remains probated until:

(1) the term of suspension has expired;

(2) all other terms or conditions of probation have been fulfilled; and

(3) a written request for reinstatement has been received by the director from the registrant, unless the probation has been revoked by the director under subsection (e) of this section; or

(4) the registration has been revoked under §13.274 of this title (relating to Revocation).

(e) Revocation after probation. Before reinstatement, a probation under this section may be revoked upon a showing that a material term or condition has been violated before the expiration date of the probation, regardless of when the petition is filed.

(f) Upon revocation of the probation, the full term of suspension must be imposed with credit for all time already served on that probation.

(g) Hearing. Upon probation under this section, the registrant may request a hearing, unless otherwise stated in the Act. If the director prevails at the hearing, the director may issue a final order of probation or reprimand.

§13.277. Voluntary Surrender. (a) Grounds. A registrant may desire to voluntarily surrender a registration:

(1) as part of an employee termination agreement;

(2) as part of a plea bargain to a criminal charge;

(3) as part of an agreed settlement of registration action or other administrative action by another federal or state health regulatory agency; or

(4) for another reason.

(b) Term. A registrant may surrender a registration either permanently or for a stated term.

(c) Effective dates. For a voluntary surrender:

(1) its beginning date is the date stated in the request or, if none, the date it was received by the director;

(2) its ending date is the date stated in the request or, if none, it will be construed as a permanent surrender; and

(3) a permanent surrender has no ending date.

(d) Procedure. A registrant may voluntarily surrender a registration by sending, or causing to be sent, a signed, written request to the director, who may accept or reject the request. The signed written request must indicate that the registrant understands the consequences of the document being signed. The director may accept a request for voluntary surrender submitted to the director in any other form that indicates the registrant intends to voluntarily surrender the registration to the director.

(e) Liberal construction. The director may liberally construe the intent of a request and may, specifically, construe the surrender of a single registration to be a surrender of all other registrations held under this chapter, unless the request expressly states otherwise. The surrender should include a summary recitation of the reason for the surrender.

(f) Effect of surrender. If accepted, the registrant is no longer registered under either type of surrender:

(1) effective on the beginning date of the surrender; and

(2) until the person applies for and meets the requirements of a new registration.

(g) Denial after surrender. In case of a reapplication, the director will deny the new registration based upon a failure to meet the current minimum standards for registration. The director may:

(1) approve the new registration and impose a previously agreed condition, such as suspension, probated term of suspension; or

(2) deny a new registration of the same or other type based solely upon a voluntary surrender:

(A) if permanent; or

(B) if for a term that has not yet expired.

§13.278. Cancellation. (a) Grounds. The director may cancel a registration if the director issued the registration in error.

(b) Hearing. Upon cancellation under this section, the registrant may request a hearing, unless otherwise stated in the Act. If the director prevails at the hearing, the director may issue a final order of cancellation.

Subchapter N. Administrative Penalties and Hearings

§13.301. Informal Hearing. (a) A panel shall convene at the timely request of a person receiving an administrative penalty in dispute and shall consist of the Manager, or designee, of the department's Narcotics Regulatory Program, and one or more of the following:

(1) Supervisor, or designee, of Controlled Substances Registration Section, for violations relating to registration and related record requirements;

(2) Supervisor, or designee, of Texas Prescription Program, for violations relating to prescriptions and related record requirements;

(3) Supervisor, or designee, of Precursor Chemical/Laboratory Apparatus Section, for violations relating to precursor chemical/laboratory apparatus or related record requirements; and

(4) any other member as may be appointed by the Manager of the Narcotics Regulation Bureau.

(b) The panel shall convene the informal hearing at the department or at another location specifically designated by the panel.

§13.302. Hearing Procedures. (a) An informal hearing shall not be subject to the rules of evidence and civil procedure except to the extent necessary for the orderly conduct of the hearing. The department will summarize the nature of the violation and penalty, and discuss the factual basis for such. The registrant or permit holder will be afforded an opportunity to respond to the allegations verbally and/or in writing.

(b) Formal hearing procedures shall follow the process set forth in Chapter 2001, Government Code.

§13.303. Mailing Address. (a) The director will send all correspondence to the person's most current address contained in the director's files.

(b) The person holding the registration or permit has the responsibility to update any information, including but not limited to mailing address, as required by §13.208 of this title (relating to Requirement to Update Information).

(c) If mailed, all correspondence is presumed to have been received by the person on the third business day after the date of mailing.

§13.304. Request for Hearing. To be properly addressed, a request for hearing must be mailed or sent by facsimile to the director at the return address included in the director's notice of administrative penalty, or if none, to the director at the address of the Narcotics Regulation Bureau indicated in §13.7 of this title (relating to Telephone Number and Address - Narcotics Regulation Bureau) or by e-mail to tppcsr@txdps.state.tx.us.

§13.305. Discretion. Subject to §481.302 of the Act, the department shall have discretion in determining the appropriate amount of the administrative penalty assessed for each violation.